

March 25, 2021

**Boehringer Ingelheim
Animal Health USA Inc.**

www.boehringer-ingelheim.us

Attn: Robert Miller
VIA CDX PORTAL
Document Processing Desk – 6(a)(2)
Office of Pesticide Programs
US Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-3553

Leann McAlister
3239 Satellite Blvd.
Duluth, GA 30096

SUBJECT: Resubmission of all 2018 and 2019 FIFRA Section 6(a)(2)
Aggregate Incident Reports for Frontline Spot-On Products

Per your request during our meeting on March 24, 2021, we are resubmitting all of the EPA Quarterly Aggregate Reports for 2018 and 2019 in support of EPA's preparation for a congressional inquiry into all spot-on pet products resulting from the recent Seresto collar articles.

Please note that all of these reports have been previously submitted via hard copy to include both Merial, Inc. and Boehringer Ingelheim Animal Health USA Inc.

If you have any questions regarding this report, please contact me at 678-638-3701 or via email at leann.mcalister@boehringer-ingelheim.com.

Sincerely,



Leann McAlister
Regulatory Affairs

Enclosure

November 18, 2019

Document Processing Desk – 6(a)(2)
Office of Pesticide Programs
US Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-3553

Boehringer Ingelheim
Animal Health USA Inc.

www.boehringer-ingelheim.us

Leann McAlister
3239 Satellite Blvd.
Duluth, GA 30096

SUBJECT: FIFRA Section 6(a)(2) Aggregate Incident Reports for 3Q19
(01Jul19 through 30Sep19)
Human and Domestic Animals in the US and Extraterritorial
Associated with the Following Boehringer Ingelheim
Registrations:

- FRONTLINE® Spray Treatment, EPA Reg. No. 65331-1
- FIPAIRA® for Cats (formerly FRONTLINE® Top Spot for Cats), EPA Reg. No. 65331-2
- FIPAIRA® for Dogs (formerly FRONTLINE® Top Spot for Dogs), EPA Reg. No. 65331-3
- FRONTLINE® Plus for Cats, EPA Reg. No. 65331-4
- FRONTLINE® Plus for Dogs, EPA Reg. No. 65331-5

Please find enclosed the FIFRA 6(a)(2) Aggregate Incident Report for 3Q19, submitted in duplicate per the EPA's request on 30Nov12. Aggregate reports for humans (HD/HE: Minor/Unknown) and domestic animals are submitted quarterly. This report is also being provided as a .pdf file on CD-ROM per EPA's communication on 03Sept14. Since these products are produced and sold worldwide, Boehringer Ingelheim is providing worldwide reporting of adverse events for the aforementioned products.

If you have any questions regarding this report, please contact me at 678-638-3701 or via email at leann.mcalister@boehringer-ingelheim.com.

Sincerely,

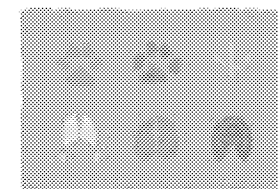


Leann McAlister
Regulatory Affairs

Enclosures

FRONTLINE BRAND PRODUCTS

EPA Quarterly Aggregate Report



Number of Incidents and Adverse Effects Reported by Exposure Type and Severity Category (USA)

Reporting Period: 01-Jul-2019 to 30-Sep-2019

Product Family: Frontline Products (include non-specific)

Generic Name / USA Registration Number	Total Incidents	H-D Human - Minor Effects	H-E Human - Unknown, Unspecified or Delayed Effects	D-A Domestic Animal - Death	D-B Domestic Animal - Major Effects	D-C, D-D, D-E Domestic Animal - Moderate, Minor, Unknown or Unspecified
FIPRONIL 10%/S METHOPRENE 12% SPOT ON / 65331-4	622	3	16	18	7	578
FIPRONIL 10%/S METHOPRENE 9% SPOT ON / 65331-5	1,204	10	17	31	14	1,132
FIPRONIL SPOT ON DOG / 65331-3	1	0	0	0	0	1
FIPRONIL SPRAY / 65331-1	15	0	1	1	0	13
Totals	1,842	13	34	50	21	1,724

USA off-Label species totals are included

Report printed on 25-Oct-2019 at 8:30:45PM

Report : D:\Assured\crystal_reports\EPAreport.p1.4.rpt

Page 1 of 4

v1.3

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00004

Use in Off-Label Species (USA)

Reporting Period: 01-Jul-2019 to 30-Sep-2019

Product Family: Frontline Products (include non-specific)

Generic Name / Registration Number Species	Total Incidents	D-A Domestic Animal - Death	D-B Domestic Animal - Major Effects	D-C, D-D, D-E Domestic Animal - Moderate, Minor, Unknown or Unspecified
FIPRONIL 10%/S METHOPRENE 12% SPOT ON / 65331-4	2	1	0	1
Ferret	1	1	0	0
Rabbit	1	0	0	1
FIPRONIL 10%/S METHOPRENE 9% SPOT ON / 65331-5	10	0	0	10
Feline	10	0	0	10
Totals	12	1	0	11

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

Number of Incidents and Adverse Effects Reported by Exposure Type and Severity Category (Extraterritorial)

Reporting Period: 01-Jul-2019 to 30-Sep-2019

Product Family: Frontline Products (include non-specific)

Generic Name / USA Registration Number	Total Incidents	H-D Human - Minor Effects	H-E Human - Unknown, Unspecified or Delayed Effects	D-A Domestic Animal - Death	D-B Domestic Animal - Major Effects	D-C, D-D, D-E Domestic Animal - Moderate, Minor, Unknown or Unspecified
FIPRONIL 10%/S METHOPRENE 12% SPOT ON / 65331-4	263	1	1	5	2	254
FIPRONIL 10%/S METHOPRENE 9% SPOT ON / 65331-5	315	2	0	4	6	303
FIPRONIL SPOT ON CAT / 65331-2	194	0	0	3	4	187
FIPRONIL SPOT ON DOG / 65331-3	242	0	0	3	4	235
FIPRONIL SPRAY / 65331-1	129	6	0	0	5	118
Frontline (Non-specific) / Frontline (Non-specific)	1	0	0	0	0	1
Totals	1,144	9	1	15	21	1,098

Extraterritorial off-Label species totals are included

Report printed on 25-Oct-2019 at 8:30:45PM

Report : D:\Assured\crystal_reports\EPAreport.p1.4.rpt

Page 3 of 4

v1.3

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00006

Use in Off-Label Species (Extraterritorial)

Reporting Period: 01-Jul-2019 to 30-Sep-2019

Product Family: Frontline Products (include non-specific)

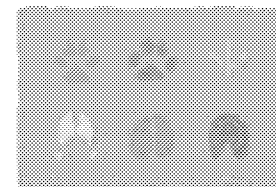
Country	Total Incidents	D-A Domestic Animal - Death	D-B Domestic Animal - Major Effects	D-C, D-D, D-E Domestic Animal - Moderate, Minor, Unknown or Unspecified
Generic Name / USA Registration Number Species				
FIPRONIL 10%/S METHOPRENE 12% SPOT ON / 65331-4	2	0	0	2
Canine	2	0	0	2
FIPRONIL 10%/S METHOPRENE 9% SPOT ON / 65331-5	1	0	0	1
Feline	1	0	0	1
FIPRONIL SPOT ON DOG / 65331-3	3	0	1	2
Feline	2	0	0	2
Rabbit	1	0	1	0
FIPRONIL SPRAY / 65331-1	1	0	0	1
Avian	1	0	0	1
Totals	7	0	1	6

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

EPA Report


 Worldwide Adverse Event Reports Involving - Animal Cases
 Reporting Period: 01-Jul-2019 to 30-Sep-2019

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
23-Jul-2019	UAE; 19AR000021; Provincia de Buenos Aires; Argentina	Species: Canine Breed: Poodle (Miniature) Sex: F Sex qualifier: - Age: 2.00 Year(s) Weight: 2 - 3 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	20-Jun-2019	20-Jun-2019	0 Day(s)	D-D	On 22 July the reported by pet owner Mia, 2 years old, 2 to 3 kg, canine, Poodle miniature, good reproductive status received FRONTLINE PLUS 0-10 KG, batch unknown, expiry unknown topical route, in shoulder blades, dose 0.67 ml, administered by owner on 20 June 2019, 30 day after product administration the animal continues having fleas. She does not make environmental treatment.
07-Aug-2019	UAE; 19AU000832; VIC; Australia	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	06-Aug-2019	07-Aug-2019	1 Day(s)	D-C	As reported by the attending veterinarian, a dog (signalment otherwise unknown) was administered an unknown dose of FRONTLINE PLUS FOR DOGS (product unsubstantiated, batch and expiry unknown) by the groomer on 6 AUG 2019 for flea and tick control. The next day the dog presented to the clinic with drooling and trembling. It is unknown if the dog has been treated and the condition was ongoing at the time of reporting. This is the extent of the information available.
23-Aug-2019	UAE; 19AU000892; -; Australia	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown	23-May-2019*	23-Aug-2019*	31 Day(s)	D-D	As reported by the owner, two cats (signalment otherwise unknown) were treated topically with FRONTLINE PLUS FOR CATS (100 g/L Fipronil, 120 g/L (S)-Methoprene, Batch and expiry unknown) each month by the owner (estimated starting date as 23 MAY 2019 for reporting purposes). The owner reports that she is still seeing fleas (estimated last dose given 23 JUL 2019). At the time of reporting the animal had not been treated and the condition was ongoing. This is the extent of the information available.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 1 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

v1.2

ED_005739D_00014390-00008

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
23-Aug-2019	UAE; 19AU000896; QLD; Australia	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: X Sex qualifier: Unknown Age: 9.00 Year(s) Weight: Unknown	3	3	0	to Company Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-Jan-2016*	23-Aug-2019*	22 Day(s)	D-D	As reported by the owner, 3 cats; 2 Males and 1 Female, Domestic Short Hairs (signalment otherwise unknown) were treated with FRONTLINE PLUS FOR CATS (100 g/L Fipronil, 120 g/L (S)-methoprene. Batch and expiry unknown) applied topically each month by the owner (estimated starting date as 1 JAN 2016 for reporting purposes). The owner reports that she is still seeing fleas (last dose administered approx 1 AUG 2019). At the time of reporting the animals had not been treated and the condition was ongoing. This is the extent of the information available.
27-Aug-2019	UAE; 19AU000902; VIC; Australia	Species: Feline Breed: Ragdoll Sex: F Sex qualifier: Neutered Age: 6.00 Year(s) Weight: 5 kg*	1	1	0	Product used: FIPRONIL SPRAY Other products used: Milbemax (milbemycin oxime, praziquantel) worming tablet; F3 vaccination (brand not provided); Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	24-Aug-2019	24-Aug-2019	0 Day(s)	D-C	As reported by the owner, Pepper an approximately 6 year old, approximately 5kg, Female Desexed Ragdoll was topically administered an unknown quantity of FRONTLINE SPRAY (batch and expiry unknown) by the vet for parasite control on 24 AUG 2019. The cat also received a Milbemax (milbemycin oxime, praziquantel) worming tablet and F3 Vaccination (brand not disclosed) at the same time. The cat was noted to groom the Frontline spray off her coat after application. Approx. 6 hours after administration, the patient experienced vomiting, yawning, lip smacking, diarrhoea. On 25 AUG 2019 drooling was also noted, veterinary treatment was sought. The patient was administered a Cerenia (maropitant) injection and Losec (omeprazole) 10mg tablets and was discharged later that day. On 26 AUG 2019 the cat presented to an emergency clinic still drooling, and an ulcer on the tongue was discovered. She was treated with buprenorphine, and maropitant. 27 AUG 2019 the cat represented to the GP clinic with ongoing diarrhoea and is now off food. Treatment was offered but declined. At the time of reporting, the condition is ongoing. This is the extent of the information available.
06-Sep-2019	UAE; 19AU000937; ACT; Australia	Species: Canine Breed: Maltese Sex: M Sex qualifier: Unknown Age: 3.00 Month(s) Weight: Unknown	1	1	1	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: Drontal Allwormer for small dogs and puppies; Companion C3; Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	09-May-2019	20-May-2019	11 Day(s)	D-A	As reported by the regulatory authority, a male Maltese cross Poodle born on 14 FEB 2019 was administered a Companion C3 vaccine on 26 APR 2019. On 9 MAY 2019 the puppy was administered an allwormer (Drontal) and had flea control applied (FRONTLINE PLUS). 14 MAY 2019 – The puppy had a microchip implanted. 18 MAY 2019 – The puppy came into the possession of a new owner. 20 MAY 2019 – The puppy was vomiting. 21 MAY 2019 – The puppy was anorexic, weak and vomiting approximately once every 30 minutes. 22 MAY 2019 – In the afternoon the puppy was presented to a vet clinic. Clinical examination revealed a weight of 1.06 kg, extremely weak, recumbent, unable to right self, head held backward, pale mucous membranes, temperature 37.3 C, and a congenital abnormality of the prepuce. A CPV faecal antigen test was negative. The puppy was assessed as being severely dehydrated, in shock and ill-thrift. The puppy was hospitalised, warmed and placed on IV fluids. A blood test revealed hypoglycaemia and the puppy was treated with multiple SC injections of glucose. Urinalysis revealed: USG: 1.025, Urobilinogen: normal, Protein: +++++, pH: 6, Blood: -ve, Ketone: 160, Bilirubin: -ve, Glucose: -ve. Blood tests and blood gases revealed: PCV/TP: 33/30, low blood pH and pCO2, high pO2, and decreased potassium, sodium, chloride, bicarbonate and haematocrit. In the evening the puppy ate a small amount of food

N/A signifies the information for this field is either not available or not applicable

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

Report printed on 25-Oct-2019 at 8:39:59PM

*indicates Approximate date or weight

Page 2 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00009

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											and was able to stand. An injection of antibiotic (amoxicillin clav) was administered and IV fluids continued. 23 MAY 2019 – The puppy was still in hospital. A blood smear revealed mild anisocytosis, adequate platelets and approximately 10% of the neutrophils were band neutrophils. Clinical examination revealed very pale mucous membranes, a heart rate of 200+ bpm, and a temperature of 38.2 C, but the puppy was brighter, eating well and urinating. Blood tests revealed: Blood gas pH 7.175 (7.3 -7.4), K+ 3.8, Na+ 134, Cl 109, glucose 2.7, SBE -17.8, Hct 31.5%, PCV/TP 35/31. Blood glucose
13-Sep-2019	UAE; 19AU000970; VIC; Australia	Species: Canine Breed: Doberman Sex: M Sex qualifier: Neutered Age: 1.00 Year(s) Weight: 37 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-Sep-2019*	07-Sep-2019*	6 Day(s)	D-D	As reported by the owner, Charly a 1 year old, 37kg, Male neutered Doberman received one dose unit (2.68ml pipette) of FRONTLINE PLUS FOR DOGS L 20-40kg (100g/L fipronil / 90g/L (S)-methoprene, BA: T60406AX EXP: 01/2022) applied topically by the owner for flea and tick control on approx 1 SEP 2019. Approx 7 days after product application a small scab at the application site was noted. The owner further noted a rash and the skin seemed red and blotchy near the site of application. The owner applied cortisone cream, no veterinary treatment has been sought and the current condition of the dog is unknown. This is the extent of the information available.
09-Jul-2019	UAE; 19BE000088; -; Belgium	Species: Canine Breed: - Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	09-Jul-2016*	09-Jul-2016*	N/A	D-D	Via via a call center acat and dog owner has a flea infestation since years despite the use of flea collars, FRONTLINE Combo and other products. No other information was provided.
09-Jul-2019	UAE; 19BE000089; -; Belgium	Species: Feline Breed: - Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	09-Jul-2016*	09-Jul-2016*	N/A	D-D	Via via a call center a cat and dog owner has a flea infestation since years despite the use of flea collars, FRONTLINE Combo and other products. No other information was provided.
15-Jul-2019	UAE; 19BE000099; -; Belgium	Species: Canine Breed: - Sex: U Sex qualifier: Unknown Age: -	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products	03-Jul-2019	15-Jul-2019	12 Day(s)	D-D	As reported by email by the animal owner, her dog (age, weight, breed not given) received FRONTLINE Spot on Dog medium (batch, expiry date, route location, dose not given) administered by the owner on 03JUL19. The product was bought via a Dutch website (Medpets). Fleas were seen 15 JUL19. The owner and her mother also had bites from fleas. She asked for a clarification. BI

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 3 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

v1.2

ED_005739D_00014390-00010

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: Unknown				Route: Topical / Cutaneous Was the product used ok?: Unknown to Company					provided her with detailed information on flea infestations in general and on the methods to tackle this problem. No other information is available.
04-Sep-2019	UAE; 19BE000111; -; Belgium	Species: Canine Breed: Maltese Sex: F Sex qualifier: - Age: 16 months Weight: 5 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	23-May-2019	10-Aug-2019	18 Day(s)	D-D	As reported by the animal owner, his dog (Maltese, female, 16m, about 5 kg) was treated for the first time with FRONTLINE Spot on on 23 April, then 23 June and the last time on 23 July 2019. No flea treatments were ever given before that period. On about 10 AUG fleas were observed (i.e. about 18 days after last treatment). The dog has also pruritis and some hair loss. The dog is at least once per month bathed and has access to the garden and regularly meets other dogs. Fleas are combed but are observed recurrently.
05-Sep-2019	UAE; 19BE000128; -; Belgium	Species: Canine Breed: Pomeranian Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	05-Sep-2019	06-Sep-2019	1 Day(s)	D-D	Via the Dutch BI subsidiary a complaint was received: on 6 SEP 19, i.e. one day after administration of FRONTLINE Spot On S (dd 5 SEP19) fleas were seen on a Pomeranian of which the age and weight are unknown (acc to the reporter). At time of administration fleas were present (no ticks). This product has been used in the past. Two times a flea infestation in the household was observed despite the use of the product. No more information was given. MAH comment: despite efforts to contact the owner (per email and telephone), no response was received.
01-Jul-2019	UAE; 19BR003207; SE; Brazil	Species: Canine Breed: Poodle (Miniature) Sex: M Sex qualifier: Unknown Age: 9.00 Year(s) Weight: 7 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	24-Apr-2019	01-Jul-2019	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, Sati, a male Poodle of 9 years old and 7 kg, was treated with one vial of FRONTLINE SPOT-ON DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 24 May 2019 and 24 Jun 2019, for tick treatment. Lack of efficacy is suspected because the pet remains with ticks. Environment treated with an unknown product. FL was applied for the first time on 24 Apr 2019. No further information is expected.
01-Jul-2019	UAE; 19BR003213; SP; Brazil	Species: Canine Breed: Lhasa Apso Sex: F Sex qualifier: Unknown Age: 7.00 Year(s) Weight: 7.4 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	06-Jan-2018*	30-Jun-2019	24 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Nicole, a female Lhasa Apso of 7 years old and 7.4 kg, received FRONTLINE PLUS DOG S (014/18A, exp date Apr 2020, topical, btw the shoulder blades), administered by the reporter on 6 Jun 2019 for flea and tick prevention. Lack of efficacy is suspected because he found 3 live ticks attached to his pet on 30 Jun 2019 and removed them. FL was used in the past with no issue (dose frequency - monthly, date of first administration was not provided - 6 Jan 2018*). The environment has been treated with Butox®. No further information is available.

N/A signifies the information for this field is either not available or not applicable

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

Report printed on 25-Oct-2019 at 8:39:59PM

*indicates Approximate date or weight

Page 4 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00011

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
02-Jul-2019	UAE; 19BR003219; PR; Brazil	Species: Feline Breed: Feline various breeds Sex: X Sex qualifier: Unknown Age: 9.00 Year(s) Weight: 3.5 kg	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-Jan-2018*	02-Jul-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, two mixed breed cats (Tiger, male, 9 years old and 3.5 kg; Furiosa, female, 5 years old and 2.5 kg), were treated with one vial of FRONTLINE PLUS CATS (FL) (013/18A, Jan 2020, topical, btw the shoulder blades), applied by the reporter on 29 Jun 2019, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. Environment treated with deltamethrin. FL has been applied monthly since date not specified (1 Jan 2018 - chosen at random). No further information is expected.
02-Jul-2019	UAE; 19BR003220; SP; Brazil	Species: Canine Breed: Large crossbred (>20 Kg) Sex: F Sex qualifier: Unknown Age: 4.00 Year(s) Weight: 30 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	15-Jun-2019	02-Jul-2019	17 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Nina, a female large crossbred dog of 4 years old and 30 kg, was treated with one vial of FRONTLINE SPOT-ON DOGS L (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied to each one by the reporter on 15 Jun 2019, for flea treatment. Lack of efficacy is suspected because the animals remain with fleas. Environment not treated. FL has been applied every 3 months with no issue since date not specified (1 Jan 2018 - chosen at random). Similar case reported on 19BR003221. No further information is expected.
02-Jul-2019	UAE; 19BR003221; SP; Brazil	Species: Canine Breed: Medium crossbred (10 - 20 Kg) Sex: F Sex qualifier: Unknown Age: 6.00 Year(s) Weight: 15 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Overdose)	15-Jun-2019	02-Jul-2019	17 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Mel, a female medium crossbred dog of 6 years old and around 15 kg, was treated with one vial of FRONTLINE SPOT-ON DOG L (FL) (lot and exp date are unknown, topical, btw the shoulder blades, overdose), applied to each one by the reporter on 15 Jun 2019, for flea treatment. Lack of efficacy is suspected because the animals remain with fleas. Environment not treated. FL has been applied every 3 months with no issue since date not specified (1 Jan 2018 - chosen at random). Similar case reported on 19BR003220. No further information is expected.
02-Jul-2019	UAE; 19BR003224; PR; Brazil	Species: Canine Breed: Medium crossbred (10 - 20 Kg) Sex: M Sex qualifier: Unknown Age: 14.00 Year(s) Weight: 15 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	28-Jun-2019	02-Jul-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Boris, a male medium crossbred dog of 14 years old and 15 kg, was treated with one vial of FRONTLINE SPOT-ON DOGS M (FL) (015/18B, Apr 2020, topical, btw the shoulder blades), applied by the reporter on 28 Jun 2019, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. Environment not treated. FL was applied in the past with no issue, but the dose frequency is unknown. No further information is expected.
02-Jul-2019	UAE; 19BR003228; PR; Brazil	Species: Canine Breed: Canine various breeds Sex: M Sex qualifier: Unknown Age: 18.00	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other	14-Jun-2019	02-Jul-2019	18 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via distributor, two male dogs (Nicky, a Maltese of 3 years old and around 8 kg; Fred, a Yorkshire of 18 months old and around 8 kg), were treated, for the first time, with one vial of FRONTLINE PLUS DOG S (lot and exp date are unknown, topical, btw the shoulder blades), applied to each one by the reporter on 14 Jun 2019, for flea treatment. Flea infestation was seen 1 week prior to FL. Lack of efficacy is suspected because the animals remain with fleas.

N/A signifies the information for this field is either not available or not applicable

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

Report printed on 25-Oct-2019 at 8:39:59PM

*indicates Approximate date or weight

Page 5 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00012

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Month(s) Weight: 8 kg				products Route: Topical / Cutaneous Was the product used ok?: Yes					Environment not treated and the dogs have no outdoor access. No further information is expected.
03-Jul-2019	UAE; 19BR003235; SP; Brazil	Species: Canine Breed: Pinscher (Miniature) Sex: M Sex qualifier: Unknown Age: 12.00 Year(s) Weight: 8.5 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	26-Jun-2019	03-Jul-2019	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Paulinho, a male Pinscher of 12 years old and around 8.5 kg, was treated with one vial of FRONTLINE SPOT-ON DOG S (FL) (014/18A, unknown exp date, topical, btw the shoulder blades), applied by the reporter on 26 Jun 2019, for flea treatment. Flea infestation one week prior to FL. Lack of efficacy is suspected because the pet remains with fleas. Environment treated with Butox®. FL has been applied every 3 months with no issue since date not specified (1 Jan 2018 - chosen at random). There is one more dog in this household that was not treated and it has no issue. No further information is expected.
03-Jul-2019	UAE; 19BR003243; PR; Brazil	Species: Canine Breed: Medium crossbred (10 - 20 Kg) Sex: M Sex qualifier: Unknown Age: 13.00 Year(s) Weight: 15 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	26-Jun-2019	03-Jul-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Mossi, a male medium crossbred dog of 13 years old and 15 kg, was treated with one vial of FRONTLINE PLUS DOG M (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 26 Jun 2019, for flea treatment. Flea infestation 4 days prior to FL. Lack of efficacy is suspected because the pet remains with fleas. Environment not treated. FL was applied 2 months ago with no issue. No further information is expected.
03-Jul-2019	UAE; 19BR003246; SP; Brazil	Species: Canine Breed: Rottweiler Sex: F Sex qualifier: Unknown Age: 2.00 Month(s) Weight: 2 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-Jul-2019	03-Jul-2019	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Pandora, a female Rottweiler of 2 months old and 2 kg, was treated, for the first time, with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 1 Jul 2019, for flea treatment. The pet was presenting fleas prior to FL. Lack of efficacy is suspected because the pet remains with fleas. Environment treated with Butox®. No further information is expected.
03-Jul-2019	UAE; 19BR003248; RJ; Brazil	Species: Feline Breed: Feline various breeds Sex: F Sex qualifier: Unknown Age: 1.00 Year(s) Weight: 3 - 4 kg	3	3	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	02-Jul-2019	03-Jul-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, three female cats (Salen, a mixed breed of 1 year old and 3 kg; Cloe, a mixed breed of 2 years old and 3 kg; Xuxu, a Siamese of 5 years old and 4 kg) were treated, for the first time, with FRONTLINE SPRAY 100 mL (FL) (lot and exp date are unknown, topical, whole body), applied by the reporter on 2 Jun 2019, for flea treatment. One day later, the owner noticed that his animals remain with fleas and they are still scratching themselves due to flea infestation. Environment not treated. No further information is expected.

N/A signifies the information for this field is either not available or not applicable

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

Report printed on 25-Oct-2019 at 8:39:59PM

*indicates Approximate date or weight

Page 6 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00013

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
02-Jul-2019	UAE; 19BR003252; -, Brazil	Species: Canine Breed: German Shepherd Dog Sex: F Sex qualifier: Unknown Age: 7.00 Year(s) Weight: 25 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	05-Jun-2019	21-Jun-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Rubi, a female German Shepherd Dog of 7 years old and 25 kg, received one pipette of FRONTLINE SPOT-ON DOGS L (FL) (lot and exp date are unknown, topical, btw the shoulder blades) administered by the reporter on 5 Jun 2019 and 1 Jul 2019 for tick treatment. Lack of efficacy is suspected because since approx. 21 Jun 2019* the owner returned to visualize live ticks on the pet. FL has been applied in the past since date not informed (2016*), dose frequency once a year (last application on Oct 2018*), with no issue. According to the reporter, she talked to many people who also complained that 'FL is no longer as effective as before', however no valid patient info was provided. Environment treated with Butox®. Similar case reported on 19BR003253. No further information is available.
02-Jul-2019	UAE; 19BR003253; -, Brazil	Species: Canine Breed: Retriever Labrador Sex: F Sex qualifier: Unknown Age: 9.00 Year(s) Weight: 25 kg	1	1	1	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	05-Jun-2019	21-Jun-2019*	16 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Belinha, a female Labrador Retriever of 9 years old 25 kg, received one pipette of FRONTLINE SPOT-ON DOGS L (FL) (lot and exp date are unknown, topical, btw the shoulder blades) administered by the reporter on 5 Jun 2019 for tick treatment. Lack of efficacy is suspected because the owner returned to see live ticks on 21 Jun 2019* and the infestation persisted until 30 Jun 2019, date which the dog died. According to the owner, Belinha was 'very old' and had arthritis, so progressively she stopped eating and became unable to walk, then she died. FL has been applied in the past with no issue, once a year (last application on Oct 2018), since date not informed (2016*). According to the reporter, she talked to many people who also complained that 'FL is no longer as effective as before', however no valid patient info was provided. Environment treated with Butox®. Similar case reported on 19BR003252. No further information is available.
03-Jul-2019	UAE; 19BR003256; SP, Brazil	Species: Canine Breed: Boxer Sex: M Sex qualifier: Unknown Age: 3.00 Month(s) Weight: 9.9 kg	1	1	0	Product used: FIPRONIL SPRAY Other products used: Vanguard®; Route: Topical / Cutaneous Was the product used ok?: No (Low dose)	02-Jul-2019	02-Jul-2019	N/A	D-B	Suspected Adverse Event: As reported by the pet owner, Apolo, a male Boxer of 3 months old and 9.9 kg, was treated, for the first time, with FRONTLINE SPRAY (FL) (003/18C, unknown exp date, topical, whole body - except the head), applied by the retail store staff member on 2 Jul 2019, for flea treatment. Vanguard® was administered on the same day, as the second dose of primary vaccination. The pet was in good health prior to FL and has no history of adverse reactions. Apolo has licked himself and ingested FL. Around 3 hours after product application, he started presenting agitation and vomiting (4 episodes) and his skin and eyes became red (Erythema). He was taken to the vet clinic and examination revealed erythema and enlarged popliteal lymph node. Enterex®, sodium bicarbonate, fluid therapy, antiemetic and antitoxic were prescribed by the vet. CBC and biochemical tests were performed. ALT and ALP showed alterations in the liver (details not provided). Hepvet® and Polaramine® were also prescribed. In addition, the pet was bathed. Apolo remains under treatment and he is showing some improvement. The vet has never seen a similar reaction before and she has a high level of suspicious that FL has caused this issue. No further information is available. UPDATE 5 JUL 2019 - The owner believes that her pet was intoxicated and had an allergic reaction caused by FL. No further information is known.
04-Jul-2019	UAE; 19BR003257; SP, Brazil	Species: Canine Breed: Canine (unknown) Sex: U	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products	01-Jul-2019*	04-Jul-2019	3 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, one dog of unknown signalment received FRONTLINE SPOT-ON (FL) (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (1 Jul

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 7 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00014

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: Unknown Age: - Weight: Unknown				used: no other products Route: unknown Was the product used ok?: Unknown to Company					2019 - chosen at random), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. FL was applied in the past with no issue (dose frequency is unknown). This is the extent of the information available.
04-Jul-2019	UAE; 19BR003258; SP; Brazil	Species: Feline Breed: Feline various breeds Sex: F Sex qualifier: Unknown Age: 5.00 Year(s) Weight: 3.8 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	19-Jun-2019	04-Jul-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, one female cat of unknown signalment received FRONTLINE PLUS CATS (FL) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (1 Jul 2019 - chosen at random), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. FL was applied in the past with no issue (dose frequency is unknown). This is the extent of the information available. UPDATE 8 JUL 2019 - Amanda, a female mixed breed cat of 5 years old and 3.8 kg, received one vial of FL, applied by the reporter on the back (incorrect application) on 19 Jun 2019, for flea treatment. The pet remains with fleas and is scratching herself due to fleas. FL has been applied every 2 months since date not specified. Environment not treated. No further information is expected.
04-Jul-2019	UAE; 19BR003262; RJ; Brazil	Species: Canine Breed: Medium crossbred (10 - 20 Kg) Sex: M Sex qualifier: Unknown Age: 10.00 Year(s) Weight: 12 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	22-Jun-2019	22-Jun-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Duck, a male crossbred dog of 10 years old and 12 kg, received one pipette of FRONTLINE PLUS DOGS M (FL) (lot and exp date are unknown, topical, btw the shoulder blades) administered by the reporter on 22 Jun 2019 for tick treatment. Lack of efficacy is suspected because the pet remains with live ticks. FL has been applied in the past, every 3 months with no issue, since date not informed. Environment not treated. No further information is available.
02-Jul-2019	UAE; 19BR003271; -; Brazil	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	3	3	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: unknown Was the product used ok?: No (Treatment / vaccination program not respected)	20-Jun-2019*	25-Jun-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, an unknown number of cats of unknown signalment received FRONTLINE SPRAY (FL) (lot, exp date, route and application site unknown), administered by the reporter on date not informed (20 Jun 2019*) for flea treatment. Lack of efficacy is suspected because the pets remained with fleas, so new administrations of FL were made with intervals of approximately 5 days (25 Jun 2019* and 30 Jun 2019*). The cats remain with fleas. This is the extent of the information available.
04-Jul-2019	UAE; 19BR003272; SP; Brazil	Species: Canine Breed: Pomeranian Sex: F	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE	14-Jun-2019	24-Jun-2019*	10 Day(s)	D-C	Suspected Lack of Efficacy Claim: As reported by the pet owner, Luna, a female Pomeranian of 5 years old and 7.2 kg, received one pipette of FRONTLINE PLUS DOGS S (FL) (lot and exp date are unknown, topical, btw the shoulder blades) administered by the

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 8 of 867

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00015

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: Unknown Age: 5.00 Year(s) Weight: 7.2 kg				9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes					reporter on 14 Jun 2019 for ectoparasite prevention. On approx. 20 Jun 2019* Luna traveled with her owner to another city and one live tick was seen on her paw on approx. the same date, however it was manually removed. One or two days later (23 Jun 2019*) Luna became 'afflicted' and started to present with panting. On date not informed (24 Jun 2019*) she also experienced intense prostration. So, she was taken to the vet clinic and, according to the reporter, on physical examination the DVM detected that Luna was feverish and tick-borne disease (babesiosis or ehrlichiosis) was suspected due to the tick infestation history. The DVM also elucidated the 'possibility of ectoparasite resistance to FL'. A CBC test was performed, which showed thrombocytopenia, and a blood sample was collected to perform a SNAP test and serology, but results are not available yet. No treatment was provided until the current moment. Due to all this, lack of efficacy is suspected by the reporter. FL has been applied in the past with no issue, since date not informed and dose frequency is unknown. No further information is available. UPDATE 22 JUL 2019 - An unknown test was performed and showed a negative result for ehrlichiosis. However, babesiosis test is still pending. No more information is known. UPDATE 25 JUL 2019 - According to the vet, Luna was also presenting back pain and sensitivity in her joints. Specific test showed a positive result for babesiosis. The pet was treated with Imizol® and is currently recovered. No further information is expected.
08-Jul-2019	UAE; 19BR003288; ES; Brazil	Species: Feline Breed: Feline various breeds Sex: M Sex qualifier: Unknown Age: 16.00 Month(s) Weight: 3 - 4 kg	2	2	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	08-Jun-2019*	08-Jul-2019	9 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, two mixed breed cats (Caramelo, male, 16 months old and 3 kg; Floquinho, male, 16 months old and 4 kg) were treated, for the first time, with FRONTLINE SPRAY (FL) (002/18, Jun 2020, topical, whole body), applied by the reporter once a week for the past 1 month (8 Jun 2019 - estimated date), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. Environment treated with Telfon®. No further information is expected.
07-Jul-2019	UAE; 19BR003291; PE; Brazil	Species: Canine Breed: German Shepherd Dog Sex: F Sex qualifier: Unknown Age: 3.00 Year(s) Weight: 27 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	21-Jun-2019	01-Jul-2019	10 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Pandora, a female German Shepherd Dog of 3 years old and 27 kg, was treated with one vial of FRONTLINE SPOT-ON DOG L (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 21 Jun 2019, for flea/tick treatment. Lack of efficacy is suspected because live ticks have been found on her dog. In addition, the pet is scratching herself due to ectoparasites. Environment treated with deltamethrin. FL has been applied every 2 months with no issue since date not specified (1 Jan 2018 - chosen at random). No further information is expected. UPDATE 15 JUL 2019 - Pandora has no outdoor access. The owner has manually removed the parasites. However, she felt a small bump on her dog's head, but she does not know if it is a tick. The pet remains with itching. No further information is known.
09-Jul-2019	UAE; 19BR003292; RJ; Brazil	Species: Canine Breed: Poodle (Miniature) Sex: F Sex qualifier:	2	2	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other	Jun-2010*	09-Jul-2019	11 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Suzi and Mel, 2 female Poodles of 9 years and 7 kg, received one pipette of FRONTLINE SPOT-ON DOGS S (FL) (014/18A, Apr 2020, topical, btw the shoulder blades) each, administered by the reporter on 28 Jun 2019 for flea treatment. Lack of efficacy is

N/A signifies the information for this field is either not available or not applicable

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Report printed on 25-Oct-2019 at 8:39:59PM

Page 9 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00016

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Unknown Age: 9.00 Year(s) Weight: 7 kg				products Route: Topical / Cutaneous Was the product used ok?: Yes					suspected because since 9 Jul 2019 the owner returned to see live fleas on the animals. FL has been administered every 3 months, 'since they were puppies' (Jun 2010*), with no issue. There is 1 cat on the same household that was also treated with FL, but with no issue. Environment treated with Cyperpour®. No further information is available.
09-Jul-2019	UAE; 19BR003295; RJ; Brazil	Species: Feline Breed: Feline (unknown) Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	2	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	09-Jul-2019	3 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, an unknown number of cats received FRONTLINE PLUS CATS (FL) (lot, exp date, route and location are unknown), applied by the reporter on 6 Jul 2019, for flea treatment. Lack of efficacy is suspected because the animals remain with fleas. In addition, they are also scratching themselves due to fleas. This is the extent of the information available. UPDATE 17 JUL 2019 - The owner was contacted and reported that she only has identified fleas in one cat (Toy, a male cat - other signalment is unknown). The pet has daily outdoor access. The environment has been treated with an anti-flea powder. FL was applied in the past with no issue (dose frequency is unknown and date of first application was not provided - 2018*). Capstar has been used, but the details were not provided. No further information is expected.
08-Jul-2019	UAE; 19BR003298; MG; Brazil	Species: Canine Breed: Shih Tzu Sex: F Sex qualifier: Unknown Age: 5.00 Year(s) Weight: 3.5 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	Jun-2018*	Jun-2018*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Amora, a female Shih Tzu of 5 years old and approximately 3.5 kg, received FRONTLINE PIPETTE (FL) (unsubstantiated) (lot and exp date unknown, topical, btw the shoulder blades) for the first time, administered by the reporter around one year ago (Jun 2018*) for flea and tick treatment. Lack of efficacy is suspected because the pet remained with fleas and ticks. The environment was treated with unknown product. No further information is available.
08-Jul-2019	UAE; 19BR003299; MG; Brazil	Species: Canine Breed: Shih Tzu Sex: F Sex qualifier: Unknown Age: 3.00 Month(s) Weight: 3 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	29-Jun-2019	29-Jun-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Linda, a female Shih Tzu of 3 months old and 3 kg, received FRONTLINE SPOT-ON DOGS S (FL) (019/18A, exp date Aug 2020, topical, btw the shoulder blades) for the first time, administered by the reporter on 29 Jun 2019 for flea and tick treatment. Lack of efficacy is suspected because the pet remains with fleas and ticks. This dog does not have outdoor access. The environment has been treated by a specialized company. No further information is available.
11-Jul-2019	UAE; 19BR003304; SP; Brazil	Species: Canine Breed: Blue Heeler Sex: X Sex qualifier: Unknown Age: 5.00 Year(s) Weight: 30 kg	2	2	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	04-Jul-2019	04-Jul-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pets owner, 2 Blue Heelers (Menina, a female of 5 years old and 30 kg; one male of 7 years old and 30 kg) received FRONTLINE SPOT-ON DOGS L (lot and exp date unknown, topical, btw the shoulder blades) for the first time, administered by the reporter on 4 Jul 2019 for flea treatment. Lack of efficacy is suspected because the pets remain with fleas. The environment has been treated with unknown product. No further information is available. UPDATE 25 JUL 2019 - The correct information is that the environment has not been treated. No further information is expected.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 10 of 867

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00017

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
10-Jul-2019	UAE; 19BR003305; RJ; Brazil	Species: Canine Breed: Yorkshire Terrier Sex: M Sex qualifier: Unknown Age: 9.00 Year(s) Weight: 4 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	06-Jul-2019	06-Jul-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Toy, a male Yorkshire of 9 years old and 4 kg, received FRONTLINE PLUS DOG S (lot and exp date unknown, topical, btw the shoulder blades), administered by the reporter on 6 Jul 2019 for flea treatment. Lack of efficacy is suspected because the pet remains with fleas and she did not visualize dead fleas so far. FL was used in the past with no issue (dose frequency is unknown and date of first administration was not provided – Aug 2010*). This dog has outdoor access. The environment has not been treated. There are 5 cats that were treated with FL and also remain with fleas living in this household (see case 19BR003306). No further information is available.
10-Jul-2019	UAE; 19BR003306; RJ; Brazil	Species: Feline Breed: Feline various breeds Sex: X Sex qualifier: Unknown Age: 4.00 Year(s) Weight: 6 - 6.5 kg	4	4	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	06-Jul-2019	06-Jul-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pets owner, 4 crossbred cats (mixed, 4 to 12 years old and 6 to 6.5 kg) received FRONTLINE PLUS CATS (lot and exp date unknown, topical, btw the shoulder blades), administered by the reporter on 6 Jul 2019 for flea treatment. Lack of efficacy is suspected because the pets remain with fleas and she did not visualize dead fleas so far. FL was used in the past with no issue (dose frequency is unknown and date of first administration was not provided – Jan 2009*). The environment has not been treated. There is a dog that was treated with FL and also remains with fleas living in this household (see case 19BR003305). No further information is available.
10-Jul-2019	UAE; 19BR003314; SP; Brazil	Species: Canine Breed: Retriever (Labrador, Yellow) Sex: F Sex qualifier: Unknown Age: 6.00 Year(s) Weight: 38 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	25-Jun-2019	25-Jun-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, a female Labrador Retriever of unknown signalment, received FRONTLINE PLUS DOGS L (FL) (lot, exp date, route and location are unknown) administered by the reporter on 25 Jun 2019 for tick treatment. Lack of efficacy is suspected because the dog remains with ticks. FL has been applied in the past, since approx. 2012* with no issue, however, dose frequency is unknown. This is the extent of the information available for now. UDPATE 15 JUL 2019 - Lana Del Rey, a female Labrador of 6 years old and 38 kg, was treated with one vial of FL (037/17A, Sep 2019, topical, btw the shoulder blades). The pet remains with ticks. Environment not treated. FL has been applied every 2 - 3 months for the past 5 years. The pet has outdoor access. No further information is expected.
11-Jul-2019	UAE; 19BR003319; SP; Brazil	Species: Feline Breed: Feline various breeds Sex: M Sex qualifier: Unknown Age: 3.00 Year(s) Weight: 15 kg	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Low dose)	05-Jul-2019	11-Jul-2019	6 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Santinho, a male mixed breed cat of 3 years old and around 15 kg was treated, for the first time, one vial of FRONTLINE SPOT-ON CAT (FL) (lot and exp date are unknown, topical, neck), applied by the reporter on 5 Jul 2019, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. Environment not treated. Similar case reported on 19BR003320. No further information is expected.
11-Jul-2019	UAE; 19BR003320;	Species: Feline Breed: Feline	1	1	0	Product used: FIPRONIL SPOT	05-Jul-2019	11-Jul-2019	6 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Xandu, a male mixed breed cat of 1 year old and around 3 kg was

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
 Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
 *indicates Approximate date or weight

Page 11 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00018

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	SP; Brazil	various breeds Sex: M Sex qualifier: Unknown Age: 1.00 Year(s) Weight: 3 kg*				ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes					treated, for the first time, one vial of FRONTLINE SPOT-ON CAT (FL) (lot and exp date are unknown, topical, neck), applied by the reporter on 5 Jul 2019, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. Environment not treated. Similar case reported on 19BR003319. No further information is expected.
11-Jul-2019	UAE; 19BR003321; PR; Brazil	Species: Canine Breed: Yorkshire Terrier Sex: F Sex qualifier: Unknown Age: 4.00 Year(s) Weight: 2 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	08-Jul-2019	09-Jul-2019	1 Day(s)	D-C	Suspected Adverse Event: As reported by the pet owner, Jade, a female Yorkshire of approximately 4 years old and 2 kg, was treated with 1 mL of FRONTLINE PLUS DOG M (FL) (039/17A, unknown exp date, topical, btw the shoulder blades - the product was fractionated), applied by the reporter on 8 Jul 2019, for flea treatment. The pet was in good health prior to FL and has no history of adverse reactions. One day later, the pet presented with application site reddening, which developed into a skin lesion today (11 Jul 2019). The pet was taken to the vet clinic, but the details were not provided. According to the owner, she applied FL (for the patient's weight) in the past with no issue. This is the extent of the information available.
12-Jul-2019	UAE; 19BR003327; SP; Brazil	Species: Canine Breed: Shih Tzu Sex: M Sex qualifier: Unknown Age: 4.00 Year(s) Weight: 9 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	02-Jul-2019	02-Jul-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Taylor, a male Shih Tzu of 4 years old and 9 kg, received one vial of FRONTLINE SPOT-ON DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 2 Jul 2019, for flea treatment. Lack of efficacy is suspected because fleas were found on her animal. Environment treated with Butox®. An unknown tablet was given to Taylor and he is currently free of fleas. FL was applied for the first time last year (2018*) with no issue. No further information is expected. UPDATE 25 JUL 2019 - The pet owner informed that she started to see fleas on Taylor again. Also, the dog is bathed 2 times per week. No further information is available.
12-Jul-2019	UAE; 19BR003328; SP; Brazil	Species: Canine Breed: Small crossbred (<10 Kg) Sex: F Sex qualifier: Unknown Age: 14.00 Year(s) Weight: 7 kg	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	01-May-2019*	01-May-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Mirela, a female small crossbred dog of 14 years old and 7 kg, received FRONTLINE SPRAY (FL) (002/18, exp date unknown, topical, behind the ears), administered by a family member on dates not informed (1 May 2019*, 1 Jun 2019* and 1 Jul 2019*) for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. This dog does not have outdoor access. There are 2 untreated cats with no fleas living in this household. The environment has not been treated. Related case reported on 19BR003329. No further information is available.
12-Jul-2019	UAE; 19BR003329; SP; Brazil	Species: Canine Breed: Small crossbred (<10 Kg) Sex: F Sex qualifier:	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products	01-May-2019*	01-May-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Lupita, a female small crossbred dog of 2 years old and 9 kg, received FRONTLINE SPRAY (FL) (002/18, exp date unknown, topical, behind the ears), administered by a family member on date not informed (1 May 2019*) for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. This dog does not

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 12 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00019

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Unknown Age: 2.00 Year(s) Weight: 9 kg				Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)					have outdoor access. There are 2 untreated cats with no fleas living in this household. The environment has not been treated. Related case reported on 19BR003328. No further information is available.
15-Jul-2019	UAE; 19BR003342; SP; Brazil	Species: Canine Breed: Retriever Labrador Sex: F Sex qualifier: Unknown Age: 11.00 Year(s) Weight: 33 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	11-Jul-2019	11-Jul-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Bela, a female Labrador of 11 years old and 33 kg, received FRONTLINE SPOT-ON DOGS L (lot and exp date unknown, topical, btw the shoulder blades), administered by the reporter on 11 Jul 2019 for tick treatment. Lack of efficacy is suspected because the pet remains with ticks. FL was used in the past with no issue (dose frequency is unknown and date of first administration was not provided; previous administration over 1 year ago - Mar 2018*). The environment has been treated with Butox®. No further information is available.
15-Jul-2019	UAE; 19BR003352; SP; Brazil	Species: Canine Breed: Lhasa Apso Sex: X Sex qualifier: Unknown Age: 7.00 Year(s) Weight: 6 - 7.5 kg	3	3	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	N/A	04-Jul-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pets owner, 3 Lhasa Apsos (Flor, a female of 13 years old and 7 kg; Sirius, a male of 7 years old and 7.5 kg; Latios, a male of 7 years old and 6 kg) received FRONTLINE SPOT-ON DOGS S (FL) (011/18B, exp date Mar 2020, topical, btw the shoulder blades), administered by the reporter on 4 Jul 2019 for flea treatment. Lack of efficacy is suspected because the pets remain with fleas. FL was used in the past with no issue (dose frequency - 3 months, date of first administration was not provided). The environment has been treated with Butox®. No further information is available.
13-Jul-2019	UAE; 19BR003362; RJ; Brazil	Species: Canine Breed: Medium crossbred (10 - 20 Kg) Sex: F Sex qualifier: Unknown Age: 6.00 Year(s) Weight: 17 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	24-Jun-2019	13-Jul-2019	19 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Pretinha, a female crossbred dog of 6 years old and 17 kg, received one pipette of FRONTLINE SPOT-ON DOGS M (FL) (X 3) (023/18A, exp date is unknown, topical, btw the shoulder blades), administered by the reporter on 24 Jun 2019 for ectoparasite prevention. Lack of efficacy is suspected because on 13 Jul 2019 two live fleas were seen on the pet, so, on the same date another pipette (same presentation and batch) was applied and Pretinha is no longer presenting ectoparasites. According to the reporter, ectoparasiticide products use to be administered monthly to the dog, however, 'sometimes the interval between administrations is a bit longer' - the date of the last administration was not informed. FL has been applied in the past with no issue, dose frequency is unknown and first application date was not provided. Pretinha usually has outdoor access. Environment not treated. No further information is available.
15-Jul-2019	UAE; 19BR003363; SC; Brazil	Species: Feline Breed: Feline various breeds Sex: X Sex qualifier: Unknown Age: 7.00 Year(s) Weight: 4 - 6 kg*	3	3	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: anti-flea shampoo;	Jun-2019*	15-Jul-2019	11 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, three mixed breeds cats (Elvis, male, 7 years old and 6 kg; Miga, male, 8 years old and 6 kg; Felicia, female, 8 years old and 4 kg) were treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied to each one by the reporter on Jun 2019* and 4 Jul 2019, for flea treatment. Lack of efficacy is suspected because the animals remain with fleas. Environment not treated. The animals

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 13 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00020

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Route: Topical / Cutaneous Was the product used ok?: Yes					were also bathed last week with an anti-flea shampoo, but it was not effective as well. FL was applied some years ago with no issue (2015*). No further information is expected.
16-Jul-2019	UAE; 19BR003364; RJ; Brazil	Species: Canine Breed: Shih Tzu Sex: F Sex qualifier: Unknown Age: 8.00 Month(s) Weight: 4 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-Jan-2019*	15-Jul-2019	2 Week(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Serena, a female Shih Tzu of 8 months old and 4 kg, received FRONTLINE PLUS DOG S (lot and exp date unknown, topical, btw the shoulder blades), administered by the reporter on 1 Jul 2019 for flea and tick prevention. Lack of efficacy is suspected because he started to see ticks on his pet 2 weeks after product administration. He removes the ticks that he visualizes. This dog has outdoor access. FL was used in the past with no issue (dose frequency - monthly, date of first administration was not provided - 1 Jan 2019*). The environment has not been properly treated. No further information is available.
15-Jul-2019	UAE; 19BR003366; SP; Brazil	Species: Canine Breed: Poodle (Miniature) Sex: F Sex qualifier: Unknown Age: 16.00 Year(s) Weight: 2.5 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	2017*	29-Jun-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Brenda, a female Poodle of 16 years old and 2.5 kg, received one pipette of FRONTLINE PLUS DOGS S (FL) (lot and exp date are unknown, topical, btw the shoulder blades) administered by the reporter on 25 Jun 2019 for ectoparasite prevention. Lack of efficacy is suspected because an unknown time after this application live fleas started to be seen on the pet, so, another pipette of same presentation (same route and location; lot and exp date are unknown) was applied on 5 Jul 2019 and the pet is still presenting fleas. FL has been administered in the past, approx. every 2-3 months, since date not informed (2017*). According to the reporter, 'from 2 months to now the product is no longer being effective', however, no details regarding these possible events were provided. Brenda use to be bathed once a week. Environment not treated. Similar case reported on 19BR003367. SAE case (same patient, another product - NEXGARD®) reported on 19BR003368. No further information is available.
15-Jul-2019	UAE; 19BR003367; SP; Brazil	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: M Sex qualifier: Unknown Age: 4.00 Year(s) Weight: 4.5 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	2017*	29-Jun-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Theo, a male Domestic Shorthair cat (crossbred) of 4 years old and 4.5 kg, received one pipette of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades) administered by the reporter on 25 Jun 2019 for ectoparasite prevention. Lack of efficacy is suspected because an unknown time after this application live fleas started to be seen on the pet, so, another pipette of same presentation (same route and location; lot and exp date are unknown) was applied on 5 Jul 2019 and the pet is still presenting fleas. FL has been administered in the past, approx. every 2-3 months, since date not informed (2017*). According to the reporter, 'from 2 months to now the product is no longer being effective', however, no details regarding these events were provided. Environment not treated. Related cases reported on 19BR003366 and 19BR003368. No further information is available.
16-Jul-2019	UAE; 19BR003369;	Species: Feline Breed: Domestic	2	2	0	Product used: FIPRONIL	30-Jun-2019	01-Jul-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Blush and Titi, 2 mixed Domestic Shorthair cats (crossbred) and of

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 14 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00021

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	SP; Brazil	Shorthair (Crossbreed) Sex: X Sex qualifier: Unknown Age: 2.50 Year(s) Weight: 3 kg				10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes					2.5 years old and 3 kg, received one pipette of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades) each, for the first time, administered by the reporter on 30 Jun 2019 for flea treatment. The ectoparasite infestation has decreased since product administration, however, eventually a few live fleas are still being seen on Blush, so lack of efficacy is suspected. The reporter is not sure if Titi is also presenting fleas because he is 'very agitated' so she can't see it, however, lack of efficacy is also suspected. FL SPRAY has been applied in the past, when the pets were 2 months old, with no issue. Environment not treated. Related case reported on 19BR003370. No further information is available. UPDATE 19 JUL 2019 - The pet owner informed that the fleas and not dying, she removes them and new fleas are visualized. The cats remain with fleas and itching more than before. They have access to the hallway of the apartment floor, were other animals also have access. The pet owner mentioned that she has two friends that are also complaining about the lack of efficacy of FRONTLINE (see case 19BR003399). No further information is expected.
16-Jul-2019	UAE; 19BR003370; SP; Brazil	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	3	3	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	1999*	1999*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, an unknown number of cats of unknown signalment received FRONTLINE (unsubstantiated; lot, exp date, route and location are unknown) an unknown number of times, approx. 20 years ago (1999*) administered by the reporter for flea treatment. According to the reporter, the product did not work and 'it does not kill fleas'. Related case reported on 19BR003369. This is the extent of the information available. UPDATE 19 JUL 2019 - The pet owner mentioned that she has two friends that are also complaining about the lack of efficacy of FRONTLINE (see case 19BR003399). No further information is expected.
17-Jul-2019	UAE; 19BR003374; SP; Brazil	Species: Canine Breed: Small crossbred (<10 Kg) Sex: F Sex qualifier: Unknown Age: 3.00 Month(s) Weight: 3 kg	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Low dose)	10-Jul-2019	17-Jul-2019*	5 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, James, a female small crossbred dog of 3 months old and 3 kg, was treated, for the first time, with FRONTLINE SPRAY (FL) (012/18B, unknown exp date, topical, parts of the body), applied by the reporter around one week ago for 3 consecutive days (10 Jul 2019, 11 Jul 2019 and 12 Jul 2019 - estimated dates), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. Environment treated with Triatox®. No further information is expected.
17-Jul-2019	UAE; 19BR003378; SC; Brazil	Species: Canine Breed: Canine various breeds Sex: X Sex qualifier: Unknown Age: 7.00 Year(s) Weight: 5 - 6 kg	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: FIPRONIL SPRAY; Route: Topical / Cutaneous Was the product used	2018*	13-Jul-2019	11 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 dogs (Romeu Francisco, a male Maltese of 7 years old and 5 kg; Duda Maria, a female small crossbred dog of 7 years old and 6 kg) were treated with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied to each one by the reporter on 2 Jul 2019, for flea treatment. The product was not effective against fleas. So, on 9 Jul 2019, the owner applied FRONTLINE SPRAY (lot and expo date are unknown, topical, whole body), but she also continues to see fleas on her animals. FL has been applied every 30 - 40 days with no issue since date not specified (2018*). Environment treated with an unknown product. There is a cat in this household with the same issue (see case 19BR003379). No further information is expected.

N/A signifies the information for this field is either not available or not applicable

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

Report printed on 25-Oct-2019 at 8:39:59PM

*indicates Approximate date or weight

Page 15 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00022

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
17-Jul-2019	UAE; 19BR003379; SC; Brazil	Species: Feline Breed: Persian (No Further Description) Sex: M Sex qualifier: Unknown Age: 9.00 Month(s) Weight: 4.1 kg	1	1	0	ok?: Yes Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: FIPRONIL SPRAY; Route: Topical / Cutaneous Was the product used ok?: Yes	Jan-2019*	12-Jul-2019	10 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Leo, a male Persian of 9 months old and 4.1 kg, was treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied to each one by the reporter on 2 Jul 2019, for flea treatment. The product was not effective against fleas. So, on 9 Jul 2019, the owner applied FRONTLINE SPRAY (lot and exp date are unknown, topical, whole body), but she also continues to see fleas on her animals. FL has been applied every 40 days with no issue since date not specified (2019*). The pet has flea allergy dermatitis. The pet was taken to the vet and was treated with a medication for allergy and other product was applied (details were not provided). The current status of the animal is unknown. Environment treated with an unknown product. Similar case reported on 19BR003378. No further information is expected.
18-Jul-2019	UAE; 19BR003388; SP; Brazil	Species: Canine Breed: Shih Tzu Sex: M Sex qualifier: Unknown Age: 3.00 Month(s) Weight: 2 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	03-Jul-2019	16-Jul-2019	13 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Simba, a male Shih Tzu of 3 months old and 2 kg, was treated, for the first time, with one vial of FRONTLINE SPOT-ON DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 3 Jul 2019, for flea treatment. Lack of efficacy is suspected because the owner noticed some fleas on his on 16 Jul 2019. Environment not treated. No further information is expected.
19-Jul-2019	UAE; 19BR003399; SP; Brazil	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	3	3	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	2019*	2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by a friend of the pets owners, an unknown number of cats of unknown signalment received FRONTLINE (FL) (unsubstantiated) (lot, exp date, route and application site unknown), administered on date not informed (2019*) for flea treatment. Lack of efficacy is suspected because the pets remained with fleas. Related cases reported on 19BR003369 and 19BR003370. This is the extent of the information available.
17-Jul-2019	UAE; 19BR003405; SC; Brazil	Species: Canine Breed: Canine various breeds Sex: F Sex qualifier: Unknown Age: 11.00 Year(s) Weight: 12 - 18 kg	2	2	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	Mar-2018	Mar-2018	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 female dogs of 11 years old (Suzie, crossbred dog, 18 kg and Lica, Dachshund, 12 kg) received FRONTLINE SPRAY 100 ML (FL) (004/17, May 2019, topical, whole body) each , administered by the reporter, from Mar 2018 to May 2019, every 15 days, for flea treatment. She has been using the same bottle for a long time, so it's possible to understand the product was underdosed. Lack of efficacy is suspected because the pets remained with live fleas during all this period. Before Mar 2018 FL was applied only once in the past, on 2015, with no issue. Both dogs use to be bathed every 15 days. The environment has not been treated. Related case was reported on 19BR003406 because after May 2019 the pets continued to be treated with same bottle (already expired), with same dose frequency, and they are still presenting live fleas. No further information is available.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 16 of 867

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00023

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
17-Jul-2019	UAE; 19BR003406; SC; Brazil	Species: Canine Breed: Canine various breeds Sex: F Sex qualifier: Unknown Age: 11.00 Year(s) Weight: 12 - 18 kg	2	2	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	Jun-2019	Jun-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 female dogs of 11 years old (Suzie, crossbred dog, 18 kg and Lica, Dachshund, 12 kg) have been receiving FRONTLINE SPRAY 100 ML (FL) (004/17, May 2019 - expired, topical, whole body) each, administered by the reporter since Jun 2019, every 15 days. Lack of efficacy is suspected because the pets remain with live fleas. The product was also administered during the period of Mar 2018 and May 2019 and same issue occurred (see 19BR003405). Before Mar 2018 FL was applied only once in the past, on 2015, with no issue. The dogs use to be bathed every 15 days. The environment has not been treated. No further information is available.
18-Jul-2019	UAE; 19BR003407; -; Brazil	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	04-Jul-2019	04-Jul-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, one dog of unknown signalment received FRONTLINE (FL) (unsubstantiated) (lot, exp date, route and application site unknown), administered by the reporter on 4 Jul 2019 for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. This is the extent of the information available.
19-Jul-2019	UAE; 19BR003409; SP; Brazil	Species: Feline Breed: Feline various breeds Sex: F Sex qualifier: Unknown Age: 5.00 Month(s) Weight: 1.5 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON; Route: auricular Was the product used ok?: No (Species not indicated / recommended)	10-Jul-2019	10-Jul-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Poty, a female crossbred cat of 5 months old and 1.5 kg, received FRONTLINE PLUS DOG S (FL) (lot and exp date unknown, topical, one drop inside each ear), administered by the reporter on 10 Jul 2019 for ear mite infection. Lack of efficacy is suspected because the pet remains with ear mite infection. Also, the cat had received 1 dose of FRONTLINE PLUS CATS (FL) (lot and exp date unknown, topical, btw the shoulder blades) on 9 Jul 2019 for flea treatment, Poty has no more fleas and no suspicion of lack of efficacy has been reported for this product. No further information is available.
19-Jul-2019	UAE; 19BR003411; RJ; Brazil	Species: Canine Breed: Medium crossbred (10 - 20 Kg) Sex: F Sex qualifier: Unknown Age: 5.00 Year(s) Weight: 18 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	19-Jul-2019*	31 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Nina, a female medium crossbred dog of 5 years old and 18 kg, was treated with FRONTLINE SPOT-ON DOG M (lot, exp date, route and location are unknown), applied by the reporter on 18 Jun 2019, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. In addition, the pet is scratching herself due to fleas. This is the extent of the information available.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 17 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00024

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
19-Jul-2019	UAE; 19BR003413; CE; Brazil	Species: Canine Breed: Small crossbred (<10 Kg) Sex: M Sex qualifier: Unknown Age: 5.00 Month(s) Weight: 9 kg	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	06-Jul-2019	06-Jul-2010*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Apolo, a male crossbred dog of 5 months old and 9 kg, received FRONTLINE SPRAY 100 ML (FL) (lot and exp date are unknown, topical, 'some regions of the body') for the first time, administered by the reporter on 6 Jul 2019 for tick treatment. Lack of efficacy is suspected because Apolo remains with live ticks. After 6 Jul 2019, FL was also applied on 9 and 11 Jul 2019 and LOE is still suspected, however, since its application has been performed differently on those 2 dates, another case was created (19BR003414). The dog use to be bathed every 7 days. The environment has been treated with K-Othrine®. No further information is available.
19-Jul-2019	UAE; 19BR003414; CE; Brazil	Species: Canine Breed: Small crossbred (<10 Kg) Sex: M Sex qualifier: Unknown Age: 5.00 Month(s) Weight: 9 kg	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	09-Jul-2019	09-Jul-2019	N/A	D-D	Suspected Lack of Efficacy Suspected Lack of Efficacy Claim: As reported by the pet owner, Apolo, a male crossbred dog of 5 months old and 9 kg, received FRONTLINE SPRAY 100 ML (FL) (lot and exp date are unknown, topical, whole body), administered by the reporter on 9 and 11 Jul 2019 for tick treatment. Lack of efficacy is suspected because Apolo remains with live ticks. The product was also applied on 6 Jul 2019 (first administration date), however, it was not administered to the dog's whole body, so another case was created (19BR003413). The environment has been treated with K-Othrine®. The dog use to be bathed every 7 days. No further information is available.
19-Jul-2019	UAE; 19BR003416; SP; Brazil	Species: Feline Breed: Feline various breeds Sex: X Sex qualifier: Unknown Age: 9.00 Month(s) Weight: 3 - 4 kg	2	2	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	11-Jul-2019	15-Jul-2019*	3 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, 1 cat of unknown signalment received FRONTLINE (FL) (unsubstantiated; lot, exp date, route and location are unknown) unknown if for the first time, administered by the reporter on 12 Jul 2019* for flea treatment. After product application, fleas were no longer seen for 2 days, however, lack of efficacy is suspected because since 15 Jul 2019* the pet owner returned to visualize live fleas on the pet. There is an unknown number of cats on the same household that also received FL. Environment factors were also not informed. This is the extent of the information available for now. UPDATE 24 JUL 2019 - The owner was contacted and reported that her two cats (Michele, a female mixed breed cat of 8 years old and 4 kg; Mikki, a male Siamese of 9 months old and 3 kg) were treated with one vial of FRONTLINE SPOT-ON CAT (topical, btw the shoulder blades), applied to each one by the reporter on 11 Jul 2019. The animals remain with fleas. Environment treated with an unknown product. FL was applied 6 months ago. No further information is expected.
22-Jul-2019	UAE; 19BR003419; SP; Brazil	Species: Canine Breed: Medium crossbred (10 - 20 Kg) Sex: X Sex qualifier: Unknown	5	4	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other	18-Jul-2019	18-Jul-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pets owner, 4 crossbred dogs (1 male and 3 females, 1 to 2 years old and 10 to 14 kg) received 1 dose of FRONTLINE PLUS DOG M (FL) (lot and exp date unknown, topical, btw the shoulder blades) each, administered by the reporter on 18 Jul 2019 for flea treatment. The animals started presenting fleas 10 days prior to FL. Lack of efficacy is suspected because the pets remain with fleas. FL was used in the past with no issue (dose frequency is unknown -

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 18 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00025

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: 1.00 Year(s) Weight: 10 - 14 kg				products Route: Topical / Cutaneous Was the product used ok?: Yes					previous administration approximately 6 months ago, date of first administration was not provided). There is a dog that was treated with FL on the same date and has no more fleas living in this household. The environment has not been treated. No further information is available.
19-Jul-2019	UAE; 19BR003422; -, Brazil	Species: Canine Breed: Canine (unknown) Sex: X Sex qualifier: Unknown Age: - Weight: 30 - 32.2 kg	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	03-Jul-2019*	07-Jul-2019*	4 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, 2 mixed dogs of unknown signalment received FRONTLINE PLUS DOGS L (FL) (lot, exp date, topical, btw the shoulder blades) unknown if for the first time, administered by the reporter on 3 Jul 2019* for flea treatment. Lack of efficacy is suspected because the pets continued to present fleas after product application. The reporter also informed that the female dog has flea allergy dermatitis and she had to be treated ('orally and cutaneous') for the issue. Due to the infestation persistence, both dogs received an unknown ectoparasiticide product 'less than 2 weeks after FL application' - 13 Jul 2019*, however, it was not informed if they remain with fleas. This is the extent of the information available for now. UPDATE 26 JUL 2019 - The owner informed that her dogs (1 female Golden Retriever of 4 years old and 32.2 kg - Maia; 1 male of approximately 30 kg - name unknown) received FL for flea prevention and got fleas after product administration. The dogs received Bravecto® and have no more fleas. FL was used in the past with no issue (dose frequency is unknown and date of first administration was not provided). The environment has not been treated. No further information is expected.
23-Jul-2019	UAE; 19BR003435; BA; Brazil	Species: Canine Breed: Small crossbred (<10 Kg) Sex: M Sex qualifier: Unknown Age: 5.00 Year(s) Weight: 4.6 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	20-Jul-2019	20-Jul-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Lupe, a male small crossbred dog of 5 years old and 4.6 kg, received 1 dose of FRONTLINE PLUS DOG S (lot and exp date unknown, topical, btw the shoulder blades) for the first time, administered by the reporter on 20 Jul 2019 for flea treatment. The dog started presenting fleas one week prior to FL. Lack of efficacy is suspected because the pet remains with fleas. There are 3 untreated dogs with no fleas living in this household. The environment has not been treated. No further information is available.
22-Jul-2019	UAE; 19BR003437; PR; Brazil	Species: Canine Breed: Medium crossbred (10 - 20 Kg) Sex: F Sex qualifier: Unknown Age: 10.00 Year(s) Weight: 12 kg	2	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	17-Jul-2019	17-Jul-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Babi, a female crossbred dog of 10 years old and 12 kg, received one pipette of FRONTLINE SPOT-ON DOGS M (FL) (lot and exp date are unknown, topical, btw the shoulder blades) for the first time, administered by the reporter on 17 Jul 2019 for flea treatment. Lack of efficacy is suspected because the pet remains with live fleas. There is one dog on the same household that was also treated with FL, but with no issue. Environment not treated. No further information is available.
22-Jul-2019	UAE; 19BR003443; SP; Brazil	Species: Feline Breed: Feline various breeds Sex: X	2	2	0	Product used: FIPRONIL SPRAY Other products	14-Jul-2019	22-Jul-2019	8 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 female mixed breed cats (Wicca, 3 years old and 2 kg; Magali, 3 years old and 2 kg) were treated with FRONTLINE SPRAY (unknown lot, expired product, topical, parts of the body), applied

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 19 of 867

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00026

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: Unknown Age: 3.00 Year(s) Weight: 2 - 5 kg				used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Low dose)					by the reporter on 14 Jul 2019, for flea control. Lack of efficacy is suspected because fleas have been found on the animals. Environment treated with Butox®. FL is applied twice a year since date not specified (Jan 2018*). There are 4 more cats in this household that were also treated with FL and they have no issue, but they were treated with an expired FL (see case 19BR003442). No further information is expected.
23-Jul-2019	UAE; 19BR003445; SP, Brazil	Species: Canine Breed: Poodle (Miniature) Sex: M Sex qualifier: Unknown Age: 2.00 Year(s) Weight: 5.5 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	2018*	15-Jul-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Nino, a male Poodle of 2 years old and 5.5 kg, received one pipette of FRONTLINE PLUS DOGS S (FL) (X 3) (014/18A, exp date is unknown, topical, btw the shoulder blades) administered by the reporter on 22 Jun 2019 for flea treatment. Lack of efficacy was suspected because one live flea was visualized on the pet, an unknown time after product administration. Due to this, another FL pipette (same presentation and batch number) was applied on 18 Jul 2019 and Nino remains presenting fleas. Before 22 Jun 2019 FL has been administered monthly, since date not informed (2018*), with no issue. Environment treated with Butox® every 15 days. No further information is available.
23-Jul-2019	UAE; 19BR003453; -, Brazil	Species: Canine Breed: Canine (unknown) Sex: F Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	23-Jul-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, one female dog of unknown signalment received FRONTLINE SPRAY 100 mL (005/18A, Sep 2020, route and location are unknown), applied by the reporter on date not specified (Jul 2019*). The owner believes that FL is not working (details were not provided). This is the extent of the information available.
23-Jul-2019	UAE; 19BR003455; SP, Brazil	Species: Canine Breed: Yorkshire Terrier Sex: M Sex qualifier: Unknown Age: 6.00 Month(s) Weight: 3 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	18-Jul-2019*	23-Jul-2019*	N/A	D-D	Suspected Adverse Event: As reported by the pet owner, Doritos, a male Yorkshire of 6 months old and 3 kg, was treated, for the first time, with one vial of FRONTLINE PLUS DOG S (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 18 Jul 2019, for flea/tick control. The pet was in good health prior to FL and has no history of adverse reactions. On 22 Jul 2019, the pet presented with application site desquamation. Doritos was bathed, but the symptom is still ongoing. No further information is available.
22-Jul-2019	UAE; 19BR003462; -, Brazil	Species: Canine Breed: Canine (unknown) Sex: F Sex qualifier: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products	2019*	2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, one female dog of unknown signalment received FRONTLINE (FL) (unsubstantiated) (lot, exp date, route and application site unknown), administered on date not informed (2019*) for flea treatment. Lack of efficacy is suspected because the pet remained with fleas. This is the extent of the information available.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 20 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00027

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: - Weight: Unknown				Route: unknown Was the product used ok?: Unknown to Company					
24-Jul-2019	UAE; 19BR003463; PE; Brazil	Species: Canine Breed: Retriever Labrador Sex: M Sex qualifier: Unknown Age: 2.00 Year(s) Weight: 28 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	11-Jul-2019	11-Jul-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Oliver, a male Labrador of 2 years old and approximately 28 kg, received 1 dose of FRONTLINE PLUS DOG L (lot and exp date unknown, topical, btw the shoulder blades), administered by the reporter on 11 Jul 2019 for flea and tick treatment. The dog started presenting fleas and ticks a few days prior to FL. Lack of efficacy is suspected because the pet owner removes the ectoparasites but continues to see new fleas and ticks on his pet. FL was used once one year ago with no issue (Jul 2018*). The environment has been treated weekly with unknown product. No further information is available.
22-Jul-2019	UAE; 19BR003464; PR; Brazil	Species: Canine Breed: Shih Tzu Sex: F Sex qualifier: Unknown Age: 6.00 Year(s) Weight: 5.5 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	24-Jun-2019	09-Jul-2019	15 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, one female Shih Tzu of 5.5 kg received FRONTLINE PIPETTE DOGS S (FL) (unsubstantiated) (lot, exp date, route and application site unknown), administered by the reporter on 24 Jun 2019. Lack of efficacy is suspected because 15 days after product administration she found 6 fleas on her pet, which was itching intensely due to the fleas. It is unknown if the dog remains with fleas. This is the extent of the information available. UPDATE 25 JUL 2019 - Meg, a female Shih Tzu of 6 years old and 5.5 kg, was treated with one vial of FL PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 24 Jun 2019, for flea control. 15 days post product application, the owner noticed that her pet started scratching herself due to flea bites. Fleas have been found since 22 Jul 2019. The owner also complains that her pet developed wounds due flea bites and she is spending a lot of money with ointment to treat Meg's wounds. Environment not treated. No further information is available.
24-Jul-2019	UAE; 19BR003467; RJ; Brazil	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: F Sex qualifier: Unknown Age: 3.00 Month(s) Weight: 2 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	24-Jul-2019	24-Jul-2019	0 Day(s)	D-D	Suspected Adverse Event: As reported by the pet owner, Kika, a female Domestic Shorthair cat (crossbred) of 3 months old and 2 kg, received FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades) for the first time, administered by the reporter on 24 Jul 2019 for ectoparasite prevention. It was not informed if Kika was in good health prior to FL use. Approx. 5-10 minutes post product administration, she presented with hypersalivation and recovered spontaneously on the same date, an unknown time later, after the owner 'removed the product from her mouth' with the help of a paper towel. According to the reporter, there is a possibility that some of the product may have dripped down the neck after application 'because the animal is too small', but is not clear if Kika actually licked the product. It is unknown if the pet has any history of AEs to other products in the past. There is 1 cat on the same household and it has not been treated with FL. No further information is available.
25-Jul-2019	UAE; 19BR003475; SP; Brazil	Species: Canine Breed: Yorkshire Terrier	1	1	0	Product used: FIPRONIL 10%/S	2014*	20-Jul-2019	10 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Belinha, a female Yorkshire of 6 years old and 4.5 kg, received FRONTLINE PLUS DOG S (011/18B, exp date unknown, topical,

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 21 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00028

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex: F Sex qualifier: Unknown Age: 6.00 Year(s) Weight: 4.5 kg				METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes					btw the shoulder blades), administered by the reporter on 10 Jul 2019 for flea and tick control. One tick was found and removed from Belinha earlier on the day of the administration. Lack of efficacy is suspected because the owner found one live tick attached to her pet 10 days after product administration and removed it. FL was used in the past with no issue (dose frequency - 2 months, date of first administration was not provided - 2014*). Also, NEXGARD (NG) (unsubstantiated) has been administered to her pet with no issue between the FL administrations. This dog has access to the street, is bathed weekly at the pet shop and taken to a country house often. The environment has not been treated. No further information is available. UPDATE 26 JUL 2019 – The mother of the pet owner informed that she continues to see ticks on Belinha. No further information is expected. UPDATE 1 AUG 2019 - Belinha was taken to the pet shop on 26 Jul 2019 and ticks were not seen. No further information is expected.
24-Jul-2019	UAE; 19BR003476; SP; Brazil	Species: Canine Breed: Lhasa Apso Sex: M Sex qualifier: Unknown Age: 5.00 Month(s) Weight: 2.1 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	30-May-2019*	22-Jul-2019	13 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Barruan, a male Lhasa Apso of 5 months old and 2.1 kg, received one pipette of FRONTLINE PLUS DOGS S (FL) (lot and exp date are unknown, topical, btw the shoulder blades) administered by the reporter on 9 Jul 2019 for tick treatment. Ticks were no longer seen, however, lack of efficacy is suspected because since 22 Jul 2019 live fleas are being seen on the pet. FL has been administered only once in the past, on 30 May 2019*, with no issue. Environment not treated. No further information is available. UPDATE 25 Jul 2019 – The pet owner informed via social media that the environment has been treated with an unknown product and the pet remains with live fleas. No further information is available.
25-Jul-2019	UAE; 19BR003478; SP; Brazil	Species: Feline Breed: Siamese Sex: F Sex qualifier: Unknown Age: 5.00 Year(s) Weight: 3.5 - 6 kg	4	4	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	10-Jul-2019*	10-Jul-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As initially reported by the retail shop staff member and later by the pet owner, 4 female Siamese cats (Miny, 10 years old and 4 kg; Meg, 5 years old and 5.5 kg; Branca, 5 years old and 6 kg; Cherry, 5 years old and 3.5 kg) received one pipette of FRONTLINE SPOT-ON CATS (FL) (lot is unknown - there is doubt if it is 007/18A or 016/18A - and exp date is also unknown, topical, btw the shoulder blades) each, administered by the reporter on 10 Jul 2019* on the cats and they are itching due to ectoparasite infestation. FL has been applied in the past (dose frequency is unknown), since date not informed (2017*), with no issue Environment has been treated with an unknown product 1 week prior to the FL application. No further information is available.
26-Jul-2019	UAE; 19BR003483; SP; Brazil	Species: Canine Breed: Shih Tzu Sex: F Sex qualifier: Unknown Age: 8.00 Year(s) Weight: 7 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	22-Jul-2019	26-Jul-2019	4 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Sindi, a female Shih Tzu of 8 years old and 7 kg, was treated with FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 22 Jul 2019, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. Environment not treated. FL was applied a long time ago (dose frequency is unknown and first application was not provided). No further information is expected.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 22 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).
Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.
Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00029

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
26-Jul-2019	UAE; 19BR003484; RJ; Brazil	Species: Feline Breed: Feline various breeds Sex: F Sex qualifier: Unknown Age: 7.00 Month(s) Weight: 2 kg	2	2	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	16-Jul-2019	16-Jul-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pets owner, Nina and Lili, 2 female crossbred cats of 7 months old and 2 kg received FRONTLINE SPRAY (FL) (002/19A, exp date unknown, topical, sprayed 2 times on the neck) for the first time, administered by the reporter on 16 Jul 2019 for flea treatment. Lack of efficacy is suspected because the pets remain with fleas . The environment has not been treated. No further information is available.
29-Jul-2019	UAE; 19BR003497; RJ; Brazil	Species: Canine Breed: Shih Tzu Sex: F Sex qualifier: Unknown Age: 3.00 Year(s) Weight: 6 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	Jul-2016*	29-Jul-2019*	12 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Nina, a female Shih Tzu of 3 years old and 6 kg, received one pipette of FRONTLINE PLUS DOGS S (FL) (007/18A, Jan 2020, topical, btw the shoulder blades), administered by the reporter on 14 Jul 2019 for ectoparasite prevention. Lack of efficacy is suspected because live fleas are being seen on Nina and she is itching due to the ectoparasite presence. FL has been applied in the past with no issue, every 30-40 days, since "the dog was a puppy" (Jul 2016*). Nina is usually bathed once a week. Environment not treated. No further information is available.
26-Jul-2019	UAE; 19BR003505; SP; Brazil	Species: Feline Breed: Feline (unknown) Sex: X Sex qualifier: Unknown Age: 6.00 Month(s) Weight: Unknown	4	4	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	02-Jul-2019	02-Jul-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pets owner via retail shop, 4 cats (2 males of 6 months to 2 years old; 2 females of 2 to 13 years old) received FRONTLINE SPOT-ON CAT (FL) (lot, exp date, route and application site unknown), administered by the reporter on 2 Jul 2019 for flea control. Lack of efficacy is suspected because the pets remain with fleas . This is the extent of the information available.
30-Jul-2019	UAE; 19BR003507; SP; Brazil	Species: Feline Breed: Feline various breeds Sex: X Sex qualifier: Unknown Age: 1.00 Year(s) Weight: 3 - 5 kg	4	4	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	23-Jul-2019*	30-Jul-2019*	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pets owner, 4 crossbred cats (2 males of 1 to 3 years old and 3 kg; 2 females of 2 years old and 3.5 to 5 kg) received 1 dose of FRONTLINE PLUS CATS (FL) (lot and exp date unknown, topical, btw the shoulder blades) each, administered by the reporter last week (23 Jul 2019*) for flea and tick prevention. Lack of efficacy is suspected because she found one flea on each cat on date not informed (30 Jul 2019*). FL was used in the past with no issue (dose frequency - 3 months, date of first administration was not provided). The cats do not have outdoor access and the owner believes that they got the fleas from pigeons that stay at the rooftop of the house. There are 2 untreated dogs living in this household. The environment has not been treated. No further information is available.
30-Jul-2019	UAE; 19BR003508;	Species: Feline Breed: Feline	6	6	0	Product used: FIPRONIL	12-Jul-2019	12-Jul-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pets owner, 6 crossbred cats (1 male and 5 females of 1 to 1.5 years old and

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 23 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00030

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	SP; Brazil	various breeds Sex: X Sex qualifier: Unknown Age: 1.00 Year(s) Weight: 3.5 - 5 kg				10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes					3.5 to 5 kg) received 1 dose of FRONTLINE PLUS CATS (FL) (lot and exp date unknown, topical, btw the shoulder blades) each, for the first time, administered by the reporter on 12 Jul 2019 for flea treatment. They started presenting fleas one week prior to FL. Lack of efficacy is suspected because the cats remain with big fleas. The animals do not have access to the street but they have access to the rooftop of the house. The environment was treated once with Butox® one day prior to FL. No further information is available.
29-Jul-2019	UAE; 19BR003510; PR; Brazil	Species: Canine Breed: Retriever (Golden) Sex: M Sex qualifier: Unknown Age: 1.30 Year(s) Weight: 45 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	12-Jul-2019	12-Jul-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Luck, a male Golden Retriever of 1.3 years old and 45 kg, received 1 dose of FRONTLINE PLUS DOG XL (008/18A, exp date Feb 2020, topical, btw the shoulder blades), administered by the reporter on 12 Jul 2019 for flea treatment. The dog started presenting fleas 15 days prior to FL. Lack of efficacy is suspected because the pet has more fleas than before treatment. Also, the product presented unusual consistency (similar to egg white) and did not spread over the skin like it usually does, so TPC case was reported on GTrack (PRID 468740). FL was used in the past with no issue (dose frequency - 2 months, date of first administration was not provided - Jun 2018*). The environment has been treated with MyPet®. No further information is available. UPDATE 7 Aug 2019 – Four pictures were received. No further information is available. 12-AUG-19 QA results received: Investigation completed for FIPRONIL 10%/S METHOPRENE 9% SPOT ON Lot# 008/18A, expiry 2020-02-29. Case investigated by France - Toulouse. Final complaint evaluation A product quality complaint for FRONTLINE PLUS DOG XL, batch number 008/18A was received by BIAH QA on the 30th of July 2019. The complaint description is: LOE and abnormal product consistency. This is the first complaint for this batch. The complaint sample is not received and pictures are not attached to this case. Not reviewed : the retention sample is stored for identification purposes. Therefore, it is not applicable to this kind of defect. Batch record review: Batch record review: S606 Manufacturing date: 12/03/2018 Expiry date: NA. Manufacturing quantity: 2399 liters Associated deviation(s): No deviation associated to this batch. Change control associated: This batch was not concerned by any change control. Observation(s): No observation associated to this batch Results of QC testing: Conform at specifications. All parameters verified during manufacturing of this batch of bulk are
28-Jul-2019	UAE; 19BR003513; SP; Brazil	Species: Canine Breed: Maltese Sex: F Sex qualifier: Unknown Age: 1.90 Year(s) Weight: 5.8 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Indication not indicated /	22-Jul-2019	22-Jul-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Jade, a female Maltese of 1.9 years old and 5.8 kg, received 1 dose of FRONTLINE SPOT-ON DOGS S (lot and exp date unknown, topical, btw the shoulder blades), administered by the reporter on 22 Jul 2019 for itch treatment. Lack of efficacy is suspected because the pet is still itching. No ectoparasites were visualized before or after product administration, however the owner believes that Jade may have fleas or ticks. FL was used for the same reason in the past with no issue (dose frequency is unknown and date of first administration was not provided). The dog is bathed weekly. The environment has been treated with unknown product. No further information is available.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 24 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00031

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
29-Jul-2019	UAE; 19BR003524; SP; Brazil	Species: Feline Breed: Feline various breeds Sex: X Sex qualifier: Unknown Age: 5.00 Year(s) Weight: 5 kg	4	4	0	recommended) Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	20-Jun-2019	20-Jun-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 6 cats of unknown signalment received FRONTLINE PLUS CATS (FL) (lot, exp date, route and location are unknown) administered by the reporter on 20 Jun 2019 for flea treatment. Lack of efficacy is suspected because since product administration live fleas are still appearing on the cats. According to the reporter, the animals don't have outdoor access. This is the extent of the information available for now. UPDATE 2 AUG 2019 – The pet owner informed that 4 crossbred cats (2 males and 2 females, approximately 5 to 10 years old and 5 kg) received FL (lot and exp date unknown, topical, btw the shoulder blades) on 20 Jun 2019 for flea treatment. They started presenting fleas approximately 1.5 months prior to FL. The cats remain with fleas. FL was used a few years ago with no issue (dose frequency is unknown and date of first administration was not provided - 2015*). The environment has not been treated. Related case reported on 19BR003564. No further information is expected.
31-Jul-2019	UAE; 19BR003528; SP; Brazil	Species: Canine Breed: Small crossbred (<10 Kg) Sex: F Sex qualifier: Unknown Age: 7.00 Year(s) Weight: 10 kg	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	01-Jul-2019*	30-Jul-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Laica, a female small crossbred dog of 7 years old and 10 kg, received FRONTLINE SPRAY 250 mL (001/18, Apr 2020, topical, whole body), applied by the reporter weekly since the beginning of the month (1 Jul 2019* to 29 Jul 2019*), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. Environment treated with an unknown product. FL was applied in the past with no issue (Jan 2018*). Similar case reported on 19BR003529. No further information is expected.
31-Jul-2019	UAE; 19BR003529; SP; Brazil	Species: Feline Breed: Feline various breeds Sex: F Sex qualifier: Unknown Age: 4.00 Year(s) Weight: 4 - 5 gms	2	2	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	01-Jul-2019*	30-Jul-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, two female mixed breed cats (Jennifer, 4 years old and 5 kg; Lindinha, 6 years old and 4 kg), received FRONTLINE SPRAY 250 mL (001/18, Apr 2020, topical, whole body), applied by the reporter weekly since 1 Jul 2019*, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. Environment treated with an unknown product. FL was applied in the past with no issue (Jan 2018*). Similar case reported on 19BR003528. No further information is expected.
31-Jul-2019	UAE; 19BR003530; AM; Brazil	Species: Canine Breed: Shih Tzu Sex: M Sex qualifier: Unknown Age: 2.00 Year(s) Weight: 8 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other	15-Jul-2019	19-Jul-2019	4 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Pablo, a male Shih Tzu of 2 years old and 8 kg, received one pipette of FRONTLINE PLUS DOGS S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), administered by the retail shop staff member on 15 Jul 2019 for tick treatment. Lack of efficacy is suspected because since 19 Jul 2019 live ticks returned to be seen on the pet. According to the reporter, the ticks use to be

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 25 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00032

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						products Route: Topical / Cutaneous Was the product used ok?: Yes					manually removed whenever they are seen. FL has been applied only 2 times in the past (Sep 2018 and Jan 2019), with no issue. Pablo use to be taken to a pet shop once a month for being bathed/groomed. Environment were treated with Barrage® and Butox®. No further information is available.
31-Jul-2019	UAE; 19BR003535; SP; Brazil	Species: Canine Breed: Shih Tzu Sex: X Sex qualifier: Unknown Age: 3.00 Year(s) Weight: 3 - 6 kg	3	3	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	04-Jul-2019	31-Jul-2019	27 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, three Shih Tzus (Julie, female, 3 years old and 3 kg; Nick, male, 10 years old and 5.5 kg; Luck, male, approximately 4 years old and 6 kg) were treated, for the first time, with one vial of FRONTLINE S (unknown if it was SPOT-ON or PLUS) (lot and exp date are unknown, topical, btw the shoulder blades), applied on each dog by the reporter around 4 Jul 2019, for tick treatment. Tick infestation one week prior to FL. After product application, the owner still sees live ticks of all sizes from her pets. She manually removes around 10 - 15 ticks every day. Ticks are also seen in the environment, which has not been treated. The animals have daily outdoor access. In addition, the owner also reported that Julie was apathetic for 20 days, but she is not sure if it was due to FL application (see case 19BR003536). No further information is expected.
31-Jul-2019	UAE; 19BR003536; SP; Brazil	Species: Canine Breed: Shih Tzu Sex: F Sex qualifier: Unknown Age: 3.00 Year(s) Weight: 3.000 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	04-Jul-2019	07-Jul-2019*	3 Day(s)	D-D	Suspected Adverse Event: As reported by the pet owner, Julie, a female Shih Tzu of 3 years old and 3 kg, was treated, for the first time, with one vial of FRONTLINE S (unknown if it was SPOT-ON or PLUS) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter around 4 Jul 2019, for tick treatment. Tick infestation one week prior to FL. After product application (time to onset is unknown), Julie started presenting apathy for 20 days, but the owner is not sure if it was due to FL application. However, the vet stated that was not due to FL. Other details were not provided. SLOE case reported on 19BR003535. No further information is expected.
31-Jul-2019	UAE; 19BR003537; RS; Brazil	Species: Canine Breed: Shih Tzu Sex: F Sex qualifier: Unknown Age: 55.00 Day(s) Weight: 1.2 kg	1	1	0	Product used: FIPRONIL SPRAY Other products used: AFOXOLANER 11.3 MG CHEWABLE TABLETS; Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	22-Jul-2019	22-Jul-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Nina, a female Shih Tzu of 55 days old and 1.2 kg, received FRONTLINE SPRAY (FL) (005/18A, exp date unknown, topical, whole body) for the first time, administered by the veterinarian on 22 Jul 2019 and 25 Jul 2019 for flea treatment. The dog started presenting fleas one day before first administration. Nina continued to have fleas, so NEXGARD (NG) (unsubstantiated) (lot and exp date unknown) was administered orally for the first time by the reporter on date not informed (28 Jul 2019*). Lack of efficacy is suspected because the pet remains with fleas. There is a dog that was treated with NG and has no fleas living in this household. The environment has been treated with Butox®. No further information is available.
31-Jul-2019	UAE; 19BR003539;	Species: Feline Breed: Feline	3	3	0	Product used: FIPRONIL	27-Jul-2019	27-Jul-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pets owner, 3 cats (Bebelha, female crossbred of 3 years old and 5 kg; Fia,

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 26 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00033

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	SP; Brazil	various breeds Sex: X Sex qualifier: Unknown Age: 3.00 Year(s) Weight: 5 kg				10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes					female crossbred of 3 years old and 5 kg; Bebe, male Persian of 5 years old and 5 kg) received 1 dose of FRONTLINE PLUS CATS (FL) (lot and exp date unknown, topical, btw the shoulder blades) each, administered by the reporter on 27 Jul 2019 for flea treatment. Lack of efficacy is suspected because the pets remain with fleas, apparently in greater quantity than before treatment. The owner also visualizes flea feces on the animals. The cats do not have outdoor access. The environment has not been treated. Related case reported on 19BR003540. No further information is available.
31-Jul-2019	UAE; 19BR003540; SP; Brazil	Species: Canine Breed: German Shepherd Dog Sex: F Sex qualifier: Unknown Age: 7.00 Year(s) Weight: 29 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	30-Apr-2019*	30-Apr-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Hidra, a female German Shepherd of 7 years old and 29 kg received FRONTLINE PLUS DOG L (FL) (lot, exp date, route and application site unknown), administered by the reporter 3 months ago (30 Apr 2019*) for flea treatment. The owner does not know if she applied the product correctly. Lack of efficacy is suspected because the pet remained with fleas. An unknown product was administered to the dog on date not informed and no more fleas were visualized. The environment has been treated by a specialized company every 3 months (date of the last treatment is unknown). Related case reported on 19BR003539. No further information is available.
01-Aug-2019	UAE; 19BR003542; -; Brazil	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	4	4	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	01-Aug-2019	15 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 4 dogs of unknown signalment were treated with FRONTLINE SPOT-ON (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on 17 Jul 2019, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. This is the extent of the information available.
30-Jul-2019	UAE; 19BR003543; -; Brazil	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	28-Jul-2019	28-Jul-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, one cat of unknown signalment received FRONTLINE SPOT-ON (FL) (unsubstantiated) (lot and exp date unknown, topical, btw the shoulder blades), administered on 28 Jul 2019 for flea treatment. Lack of efficacy is suspected because the pet remains with live fleas over 48 hours after product administration. This is the extent of the information available.
01-Aug-2019	UAE; 19BR003545; SP; Brazil	Species: Canine Breed: Poodle (Miniature) Sex: F Sex qualifier: Unknown Age: 5.00 Year(s) Weight: 3.6 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products	03-Jul-2019	01-Aug-2019	29 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Mel, a female Poodle of 5 years old and 3.6 kg, was treated, for the second time, with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 3 Jul 2019, for flea and tick treatment. Fleas have died. However, every day the owner finds ticks ('cayenne ticks' and another type of tick) on her dog. Environment not treated. The dog is mainly indoors but has access to the front

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
 Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
 *indicates Approximate date or weight

Page 27 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00034

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Route: Topical / Cutaneous Was the product used ok?: Yes					yard. FL was applied for the first time one year ago (Jul 2018*). No further information is expected.
01-Aug-2019	UAE; 19BR003547; SP; Brazil	Species: Canine Breed: Poodle (Miniature) Sex: F Sex qualifier: Unknown Age: 12.00 Year(s) Weight: 10 kg	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	2007*	31-Jul-2019	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Mel, a female Poodle of 12 years old and 10 kg, has been receiving FRONTLINE SPRAY 100 ML (FL) (002/18, Jun 2020, topical, whole body; low dose), administered by the reporter every 7-15 days (last application date: 24 Jul 2019) for ectoparasite prevention. The same bottle is being used since 1 Jul 2019* so it is possible to presume that the product was underdosed. Lack of efficacy is suspected because on 31 Jul 2019 live fleas and skin wounds due to the 'flea bites' started to be seen on the pet. According to the owner, Mel has flea allergy dermatitis. FL has been applied in the past with no issue, on the same dose frequency, since the dog was a puppy (2007*), always after being bathed. Environment not treated. No further information is available.
02-Aug-2019	UAE; 19BR003551; SP; Brazil	Species: Feline Breed: Feline various breeds Sex: X Sex qualifier: Unknown Age: 7.00 Month(s) Weight: 3 - 9 kg	4	4	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	24-Jul-2019	24-Jul-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pets owner, 4 crossbred cats (3 females and 1 male, 7 months to 6 years old and 3 to 9 kg) received 1 dose of FRONTLINE SPOT-ON CAT (FL) (lot and exp date unknown, topical, btw the shoulder blades) each, administered by the reporter on 24 Jul 2019 for flea treatment. The cats started presenting fleas 2 weeks prior to product administration. Lack of efficacy is suspected because the pets remain with fleas. FL was used in the past with no issue (dose frequency - 2 months, date of first administration was not provided). The environment has been treated with Butox®. No further information is available.
30-Jul-2019	UAE; 19BR003554; SP; Brazil	Species: Canine Breed: Shih Tzu Sex: M Sex qualifier: Unknown Age: 7.00 Week(s) Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	Dec-2018*	Dec-2018*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Pingo, a male Shih Tzu born on 10 Nov 2018, received FRONTLINE (FL) (unsubstantiated) (lot, exp date, route and application site unknown), administered on date not informed (Dec 2018*) for tick treatment. Lack of efficacy is suspected because the pet remained with ticks. The dog received NEXGARD (11.3 mg) (lot and exp date unknown) on date not specified (10 Jan 2019*) and no more ticks were reported. Related cases reported on 19BR003485 and 19BR003555. No further information is available.
01-Aug-2019	UAE; 19BR003558; SP; Brazil	Species: Feline Breed: Feline various breeds Sex: X Sex qualifier: Unknown Age: 8.00 Year(s) Weight: 2 - 3.5 kg	3	3	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No	25-Apr-2019*	25-Apr-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, 3 cats of unknown signalment received FRONTLINE PLUS (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter one month ago (1 Jul 2019 - estimated date) and recently (30 Jul 2019 - estimated date). Lack of efficacy is suspected because the animals keep itching themselves so much that they are hairless. FL has been applied since date not specified with no issue (dose frequency is unknown and first administration was not provided - 2018*). This is the extent of the information available. UPDATE 5 AUG 2019 - The owner informed that her cats (Otavio, male crossbred of 8 years old and 3.5 kg; Mimi, female Siamese of 8.5 years old and 2 kg; Lili, female crossbred of 8 years old and 2.5 kg) received 1 dose of

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 28 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00035

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						(Treatment / vaccination program not respected)					FRONTLINE PLUS CATS (lot and exp date unknown, topical, btw the shoulder blades) each, approximately 3 months ago (25 Apr 2019*) for flea treatment. Another application of FL was made on 25 Jul 2019. Lack of efficacy is suspected because the cats remain with fleas and itching due to the flea infestation. FL was used in the past with no issue (dose frequency - 3 months, date of first administration was not provided - 2011*). The environment has not been treated. No further information is expected.
01-Aug-2019	UAE; 19BR003561; SP; Brazil	Species: Canine Breed: Pekingese Sex: X Sex qualifier: Unknown Age: 45.00 Day(s) Weight: 0.5 - 3 kg	7	7	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	28-Jun-2019	28-Jun-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 7 mixed Pekingese from 45 days old to 1.2 years old and approx. 600 grams to 3 kg, received FRONTLINE SPRAY 100 ML (FRONTLINE) (lot and exp date are unknown, topical, whole body except the head) administered by the reporter on 28 Jun 2019 (first administration date) and 26 Jul 2019 for tick treatment. Lack of efficacy is suspected because the dogs remain with live ticks. Environment treated with an unknown product. No further information is available.
29-Jul-2019	UAE; 19BR003564; SP; Brazil	Species: Feline Breed: Feline various breeds Sex: X Sex qualifier: Unknown Age: 7.00 Month(s) Weight: 3 kg	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	20-Jun-2019	20-Jun-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 crossbred cats (Lua, female of 3 years old and 3 kg; Floc, male of 7 months old and 3 kg) received 1 dose of FRONTLINE PLUS CATS (FL) (lot and exp date unknown, topical, btw the shoulder blades) each, for the first time, administered by the reporter on 20 Jun 2019 for flea treatment. They started presenting fleas approximately 1.5 months prior to FL. Lack of efficacy is suspected because the pets remain with fleas. The cats do not have outdoor access. The environment has not been treated. Related case reported on 19BR003524. No further information is available.
04-Aug-2019	UAE; 19BR003568; SP; Brazil	Species: Canine Breed: Large crossbred (>20 Kg) Sex: M Sex qualifier: Unknown Age: 10.00 Year(s) Weight: 40 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	25-Jul-2019	25-Jul-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, one dog of unknown signalment received FRONTLINE (unsubstantiated; lot, exp date, route and location are unknown) administered by the reporter on date not informed (Jul 2019*) for flea treatment. Lack of efficacy is suspected because live fleas remained being visualized post FL. Due to this, an unknown product was administered to the animal, however, it was not informed if the ectoparasite infestation stopped. Environment treated with an unknown product. This is the extent of the information available for now. UPDATE 8 Aug 2019 – The pet owner was contacted and reported that Mike, a male crossbred dog of 10 years old and 40 kg, received FRONTLINE PLUS DOGS XL (FL) (lot and exp date are unknown, topical, btw the shoulder blades) administered on 25 Jul 2019 for flea treatment. Lack of efficacy was suspected because live fleas were still being found on the pet after product administration. Due to this, on 27 Jul 2019 Nexgard® was administered and since 29 Jul 2019 Mike is no longer presenting fleas. According to the reporter, Mike use to be taken for a walk at the park sometimes. Environment has been simultaneously treated with Neocid®. No further information is

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
 Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
 *indicates Approximate date or weight

Page 29 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00036

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											available.
06-Aug-2019	UAE; 19BR003597; RJ; Brazil	Species: Canine Breed: Medium crossbred (10 - 20 Kg) Sex: F Sex qualifier: Unknown Age: 5.00 Year(s) Weight: 13.5 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	22-Jul-2019*	22-Jul-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Nina, a female crossbred dog of 5 years old and 13.5 kg, received one pipette of FRONTLINE SPOT-ON DOGS M (FL) (lot and exp date are unknown, topical, btw the shoulder blades), administered by the reporter on approx. 22 Jul 2019* for flea treatment. Lack of efficacy is suspected because live fleas are still being seen on Nina, specially on her belly. The pet owner eventually catches the fleas from the animal. Approx. 2-3 days after product administration (25 Jul 2019*), Nina was bathed with unknown product. FL has been applied only once in the past, on Feb 2019, with no issue. Environment not treated. No further information is available.
07-Aug-2019	UAE; 19BR003599; SP; Brazil	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: M Sex qualifier: Unknown Age: 3.00 Year(s) Weight: 3.8 - 5.6 kg	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	May-2019	04-Aug-2019*	30 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 male Domestic Shorthair cats (crossbred) (Fofico, 4 years old and 5.6 kg; Miguel, 3 years old and 3.8 kg) received one pipette of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades) each, administered by the reporter on 15 Jul 2019* (estimated) for flea treatment. Lack of efficacy is suspected because 20 days after product administration (4 Aug 2019*) live fleas started to be seen on the pets again. Same issue occurred after the previous FL application performed on May 2019 (first administration date). Environment treated with an unknown product. No further information is available.
07-Aug-2019	UAE; 19BR003601; RJ; Brazil	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: F Sex qualifier: Unknown Age: 22.00 Month(s) Weight: 5.5 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	05-Jul-2019	05-Jul-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Leona, a female Domestic Shorthair cat (crossbred) of 22 months old and 5.5 kg, received one pipette of FRONTLINE CATS (FL) (unsubstantiated; lot and exp date are unknown, topical, btw the shoulder blades) administered by the reporter on 5 Jul 2019 for flea treatment. Lack of efficacy is suspected because live fleas are still seen on the pet since approx. product administration. FL has been applied only once in the past (Jun 2018*), with no issue. The cat use to be bathed once a week. Environment not treated. Similar case reported on 19BR003602. No further information is available.
07-Aug-2019	UAE; 19BR003602; RJ; Brazil	Species: Canine Breed: Small crossbred (<10 Kg) Sex: F Sex qualifier: Unknown Age: 8.00 Year(s) Weight: 8.5 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	05-Jul-2019	05-Jul-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Belinha, a female crossbred dog of 8 years old and 8.5 kg, received one pipette of FRONTLINE PLUS DOGS S (FL) (lot and exp date are unknown, topical, btw the shoulder blades) administered by the reporter on 5 Jul 2019 for flea treatment. Lack of efficacy is suspected because live fleas are still seen on the pet since approx. product administration. FL has been applied only once in the past (Jun 2018*), with no issue. The dog use to be bathed once a week. Environment not treated. Similar case reported on 19BR003601. No further information is available.
07-Aug-2019	UAE; 19BR003605;	Species: Feline Breed: Domestic	2	2	0	Product used: FIPRONIL	30-Jul-2019	Jan-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 Domestic Shorthair cats (crossbred) (Tigrão, male, 3.9 years old, 3

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 30 of 867

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

v1.2

ED_005739D_00014390-00037

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	SP; Brazil	Shorthair (Crossbreed) Sex: X Sex qualifier: Unknown Age: 2.50 Year(s) Weight: 3 - 4.5 kg				SPRAY Other products used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON; Comfortis®; Unknown shampoo/soap non ectoparasiticide; Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)					kg; Nina, female, 2.5 years old, 4.5 kg) received FRONTLINE SPRAY 250 ML (FL SPRAY) (003/18, exp date is unknown, topical, whole body) for the first time, administered by the reporter on 30 Jul 2019 for flea treatment. Lack of efficacy was suspected because the cats remained with live fleas. On 7 Aug 2019 the reporter gave them a bath with an unknown product because 'their fur were dirty'. Also on that date, after bathing the animals, FL SPRAY was applied again (same route and location) and lack of efficacy remains suspected because live fleas are still being visualized on both cats. FRONTLINE PLUS CATS (FL PLUS) (lot, exp date, route and location are unknown) was being administered to each cat, every 30 days 'since beginning of the year' (Jan to May 2019* - estimated), and same issue occurred (according to the reporter, none of the applications were effective and the flea infestation persisted). Due to this, Comfortis® was administered on date not informed (Jun 2019*) and the flea infestation kept ongoing on the pets as well. Finally, FL SPRAY has been administered, without success, on the dates previously mentioned on this report. Environment has been treated with Butox® and Pulgoff®. No further information is available.
08-Aug-2019	UAE; 19BR003606; SP; Brazil	Species: Canine Breed: Poodle (Toy) Sex: M Sex qualifier: Unknown Age: 9.00 Year(s) Weight: 8 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	30-Jul-2019	30-Jul-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Bout, a male Poodle of 9 years old and 8 kg, received 1 dose of FRONTLINE PLUS DOG S (022/18A, exp date unknown, topical, btw the shoulder blades), administered by the reporter on 30 Jul 2019 for flea treatment. The dog started presenting fleas 2 to 3 months prior to FL. Lack of efficacy is suspected because the pet remains with a high quantity of fleas. The owner removes the fleas and new fleas appear on the animal. She believes that Bout is getting the fleas during his walks. The dog is bathed weekly at home. FL was used once 7 or 8 months ago (Jan 2019*). The environment has not been treated. No further information is available.
08-Aug-2019	UAE; 19BR003612; RJ; Brazil	Species: Canine Breed: Beagle Sex: F Sex qualifier: Unknown Age: 11.00 Month(s) Weight: 8 kg	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	08-Aug-2019	08-Aug-2019	0 Day(s)	D-C	Suspected Adverse Event: As reported by the pet owner, Capitulina, a female Beagle of 11 months old and 8 kg, received FRONTLINE SPRAY 100 ML (FL) (003/17, Jan 2019 – expired, topical, back) administered by the reporter on 8 Aug 2019 for ectoparasite prevention. Shortly before the product administration, the dog had just taken a bath at the pet store and came back home 'presenting a strange behaviour'. The pet owner also noticed a swelling and erythema in the pet's mouth, which 'looked like a wound'. Two minutes after FL administration, Capitulina experienced extreme agitation, eye swelling, panting, vomiting (approx. 2 episodes), anorexia and she also began to compulsively lick the floor. According to the reporter, Capitulina did not lick her coat after FL administration and due to this the owner did not attribute the experienced symptoms to the product. She suspects that the dog may have eaten something different at the pet store or may have been gagged by some pet store employee. Capitulina was taken to the vet clinic and received fluid therapy, antitoxic medication, antiallergic medication and activated charcoal for treatment. Although symptoms have improved, the pet is currently under treatment with Celestamine®. FL has been administered monthly, with no issue, since date not informed (2018*). It is unknown if there is any history of AEs to other products in the past. No further information is available.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 31 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00038

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
09-Aug-2019	UAE; 19BR003621; RJ; Brazil	Species: Canine Breed: Small crossbred (<10 Kg) Sex: F Sex qualifier: Unknown Age: 8.00 Year(s) Weight: 8.8 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	05-Aug-2019	05-Aug-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Bolinha, a female small crossbred dog of 8 years old and 8.8 kg, received 1 dose of FRONTLINE PLUS DOG S (lot and exp date unknown, topical, btw the shoulder blades), administered by the reporter on 5 Aug 2019 for flea treatment. The animal started presenting fleas 1 week prior to FL, after the cat that lives in this house went to the neighbor's house and returned with fleas (see case 19BR003622). Lack of efficacy is suspected because the pet remains with fleas and itching due to the flea infestation. FL was used once in the past with no issue (date not informed - 2018*). The environment has not been treated. No further information is available.
09-Aug-2019	UAE; 19BR003622; RJ; Brazil	Species: Feline Breed: Feline various breeds Sex: F Sex qualifier: Unknown Age: 2.00 Year(s) Weight: 5.5 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	05-Aug-2019	05-Aug-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Fiona, a female crossbred cat of 2 years old and 5.5 kg, received 1 dose of FRONTLINE PLUS CATS (lot and exp date unknown, topical, btw the shoulder blades), administered by the reporter on 5 Aug 2019 for flea treatment. The animal started presenting fleas 1 week prior to FL, after the she went to the neighbor's house. Lack of efficacy is suspected because the pet remains with fleas and itching due to the flea infestation. FL was used once in the past with no issue (date not informed - 2018*). The environment has not been treated. Related case reported on 19BR003621. No further information is available.
12-Aug-2019	UAE; 19BR003623; PR; Brazil	Species: Canine Breed: Rottweiler Sex: F Sex qualifier: Unknown Age: 11.00 Year(s) Weight: 60 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	17-Jul-2019	17-Jul-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Ursa, a female Rottweiler of 11 years old and 60 kg, received 1.5 doses of FRONTLINE PLUS DOG XL (032/17B, exp date unknown, topical, 1 pipette btw the shoulder blades and 1/2 pipette on the tail region), administered by the reporter on 17 Jul 2019 for flea treatment. The dog started presenting fleas 10 days prior to FL. Lack of efficacy is suspected because the pet remains with fleas. FL was used in the past with no issue (dose frequency - 3 months, date of first administration was not provided - 2017*). The environment has not been treated. No further information is available.
09-Aug-2019	UAE; 19BR003627; -, Brazil	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	3	3	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown	02-Aug-2019*	02-Aug-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, 3 cats of unknown signalment received FRONTLINE (unsubstantiated; lot, exp date, route and location are unknown) administered by the reporter on 2 Aug 2019* for flea treatment. Lack of efficacy is suspected because live fleas are still being seen on the pets and they are still itching due to the ectoparasite presence. FL has been applied only once in the past, on date not informed, with no issue. This is the extent of the information available for now.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 32 of 867

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00039

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
12-Aug-2019	UAE; 19BR003630; RJ; Brazil	Species: Canine Breed: Small crossbred (<10 Kg) Sex: F Sex qualifier: Unknown Age: 4.00 Month(s) Weight: 6 kg	1	1	0	to Company Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	08-Aug-2019	08-Aug-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Flor, a female small crossbred dog of 4 months old and 6 kg, received FRONTLINE PLUS DOG S (022/18A, exp date unknown, topical, btw the shoulder blades), administered by a family member on 8 Aug 2019 for flea treatment. The dog started presenting fleas 1 month prior to FL. Lack of efficacy is suspected because the pet remains with fleas. FL was used in the past with no issue (dose frequency is unknown and date of first administration was not provided). The environment has not been treated. No further information is available.
12-Aug-2019	UAE; 19BR003631; SP; Brazil	Species: Feline Breed: Feline various breeds Sex: F Sex qualifier: Unknown Age: - Weight: 2 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	10-Aug-2019	10-Aug-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Maria, a female crossbred cat of 2 kg, received 1 dose of FRONTLINE PLUS CATS (lot and exp date unknown, topical, ears) for the first time, administered by an unknown person on 10 Aug 2019 for flea treatment. Another application of FL (lot and exp date unknown, topical, btw the shoulder blades) was made by the reporter on 11 Aug 2019. Lack of efficacy is suspected because the pet remains with fleas. The environment has not been treated. No further information is available.
13-Aug-2019	UAE; 19BR003632; DF; Brazil	Species: Canine Breed: German Shepherd Dog Sex: M Sex qualifier: Unknown Age: 2.00 Year(s) Weight: 35 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	03-Aug-2019	03-Aug-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Hulk, a male German Shepherd of 2 years old and 35 kg, received 1 dose of FRONTLINE SPOT-ON DOGS L (013/18A, exp date May 2020, topical, btw the shoulder blades), administered by the reporter on 3 Aug 2019 for flea treatment. Another application of FL was made on 8 Aug 2019. The dog started presenting fleas 3 to 4 days prior to FL. Lack of efficacy is suspected because he continues to see fleas walking on his pet. FL was used in the past with no issue (dose frequency is unknown and date of first administration was not provided - 2017*). The environment has not been treated. No further information is available.
12-Aug-2019	UAE; 19BR003633; PR; Brazil	Species: Canine Breed: Shih Tzu Sex: M Sex qualifier: Unknown Age: 6.00 Year(s) Weight: 5 kg	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the	12-Jul-2019	12-Jul-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Ciborg, a male Shih Tzu of 6 years old and 5 kg, received FRONTLINE SPRAY (003/18, exp date unknown, topical, whole body), administered by the reporter on 12 Jul 2019, 19 Jul 2019 and 12 Aug 2019 for flea treatment. The dog started presenting fleas 1 day prior to FL. Lack of efficacy is suspected because the pet remains with fleas. FL was used in the past with no issue (dose frequency is unknown and date of first administration was not provided - 2014*). The environment has been treated with Icon 10

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 33 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00040

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						product used ok?: No (Treatment / vaccination program not respected)					PM®. No further information is available.
12-Aug-2019	UAE; 19BR003637; SP; Brazil	Species: Canine Breed: Pug Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	12-Aug-2019*	12-Aug-2019*	0 Day(s)	D-C	Suspected Adverse Event: As reported by the veterinarian, one Pug of unknown signalment received FRONTLINE SPOT-ON DOGS S (lot, exp date, route and application site unknown), administered on date not specified (12 Aug 2019*). Some time after product administration the animal experienced allergic reaction, six episodes of vomiting and hyperexcitation. Signals are still ongoing. No further information is available.
12-Aug-2019	UAE; 19BR003641; RS; Brazil	Species: Canine Breed: Pinscher (Miniature) Sex: F Sex qualifier: Unknown Age: 5.00 Year(s) Weight: 1.8 - 2 kg	2	2	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	09-Aug-2019	09-Aug-2019*	0 Day(s)	D-D	Suspected Adverse Event: As reported by the pet owner, 2 female Pinschers of 5 years old (Pituca, 2 kg; Lindinha, 1.8 kg) received FRONTLINE SPRAY 100 ML (FL) (002/19, exp date is unknown, topical, btw the shoulder blades and lateral thorax) for the first time, administered by the reporter on 9 Aug 2019 for flea treatment. Both dogs were in good health prior to the application. Right after FL use (exact chronology unspecified) Pituca e Lindinha started to present with intense itching and on 11 Aug 2019 the owner also noted multiple small lumps and skin sores all over their body. According to the owner, the small lumps seen on Pituca had red colour and 'these small lumps have burst and then became wounds'. An unknown time later (11 Aug 2019*) vomiting and partial anorexia also started to occur to both dogs. At present, the reported signs remain ongoing. The dogs have not been taken to the DVM and no treatment has been provided. There is no history of AEs in the past and the animals never experienced any dermatopathies. No further information is available.
14-Aug-2019	UAE; 19BR003651; RJ; Brazil	Species: Canine Breed: Terrier (Jack Russell) Sex: X Sex qualifier: Unknown Age: 7.00 Month(s) Weight: 4.5 - 6 kg	5	5	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	Jan-2019*	05-Aug-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pets owner, 5 Jack Russell Terriers (males and females) of 7 months to 3 years old and approximately 4.5 to 6 kg received FRONTLINE SPRAY (FL) (006/18, exp date unknown, topical, whole body), administered by the reporter on date not informed (5 Jul 2019*) for flea and tick prevention. Lack of efficacy is suspected because the dogs got fleas approximately 1 month after FL. New administrations of FL were made on 12 Aug 2019, 13 Aug 2019 and 14 Aug 2019 and the pets remain with fleas. The dogs are bathed every 15 days. FL was used in the past with no issue (dose frequency - 30 to 40 days, date of first administration was not provided - Jan 2019*). There are 3 dogs treated with NEXGARD with no fleas, 1 cat treated with FRONTLINE (pipette - unsubstantiated) with no fleas and an unknown number of untreated cats with fleas living in this household. The environment has been treated with Triatox®. No further information is available.
13-Aug-2019	UAE; 19BR003658; -, Brazil	Species: Canine Breed: Medium crossbred (10 - 20 Kg) Sex: X	3	3	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON	05-Jul-2019	05-Jul-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pets owner, 3 medium crossbred dogs (Joca, male of 9 years old and 15 kg; Leão, male of 4 years old and 17 kg; Bianca, female of 8 years old and 20 kg) received 1 dose of FRONTLINE PLUS DOG M (lot and exp date unknown, topical, btw the shoulder blades) each, for the

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 34 of 867

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00041

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: Unknown Age: 4.00 Year(s) Weight: 15 - 20 kg				Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes					first time, administered by the reporter on 5 Jul 2019 for flea treatment. The dogs started presenting fleas 15 days prior to FL. Lack of efficacy is suspected because the pets remain with live fleas, bigger than before treatment and filled with blood. The animals are bathed weekly. The environment has been treated with Butox®. The reporter says that his neighbor also complained about FL, but no details were provided. Related case reported on 19BR003659. No further information is available.
13-Aug-2019	UAE; 19BR003659; -, Brazil	Species: Canine Breed: Canine various breeds Sex: M Sex qualifier: Unknown Age: 5.00 Year(s) Weight: 25 - 30 kg	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	05-Jul-2019	05-Jul-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pets owner, 2 male dogs (Negão, Pit Bull of 5 years old and 30 kg; Neguinho, large crossbred of 5 years old and 25 kg) received 1 dose of FRONTLINE PLUS DOG L (lot and exp date unknown, topical, btw the shoulder blades) each, for the first time, administered by the reporter on 5 Jul 2019 for flea treatment. The dogs started presenting fleas 15 days prior to FL. Lack of efficacy is suspected because the pets remain with live fleas, bigger than before treatment and filled with blood. The animals are bathed weekly. The environment has been treated with Butox®. The reporter says that his neighbor also complained about FL, but no details were provided. Related case reported on 19BR003658. No further information is available.
13-Aug-2019	UAE; 19BR003662; RJ; Brazil	Species: Feline Breed: Feline various breeds Sex: F Sex qualifier: Unknown Age: 5.50 Month(s) Weight: 0.5 - 1 kg	2	2	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	08-Aug-2019	08-Aug-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pets owner, 2 female crossbred cats (Molly, approximately 5.5 months old and approximately 0.5 kg; Milly, approximately 7.5 months old and approximately 1 kg) received 1 dose of FRONTLINE SPOT-ON CAT (FL) (016/18A, exp date unknown, topical, btw the shoulder blades) each, for the first time, administered by the reporter on 8 Aug 2019 for flea treatment. They were adopted already presenting fleas approximately 1 week prior to FL. Lack of efficacy is suspected because the pets remain with fleas. The cats are bathed weekly and do not have outdoor access. There are 2 untreated dogs with no fleas that live in the backyard of the house. The environment has been treated with Butox®. No further information is available.
14-Aug-2019	UAE; 19BR003668; PE; Brazil	Species: Canine Breed: Shih Tzu Sex: M Sex qualifier: Unknown Age: 10.00 Month(s) Weight: 6 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Overdose)	25-Jul-2019	25-Jul-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Rio, a male Shih Tzu of 10 months old and 6 kg, received FRONTLINE SPOT-ON DOGS M (FL) (lot and exp date are unknown, topical, btw the shoulder blades) for the first time, administered by the reporter on 25 Jul 2019 for tick treatment. Lack of efficacy is suspected because the pet remains with live ticks. The dog use to be bathed every 8 days. Environment has been simultaneously treated with Barrage®. No further information is available.
13-Aug-2019	UAE; 19BR003669; -, Brazil	Species: Canine Breed: Medium crossbred (10 - 20 Kg) Sex: M Sex qualifier: Unknown Age: 1.00 Year(s) Weight: 16 kg*	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON;	26-Jul-2019	29-Jul-2019	3 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, one dog of approx. 18 kg and unknown signalment received FRONTLINE (unsubstantiated) (FL) (lot, exp date, route and location are unknown) administered by the reporter on 26 Jul 2019 for flea treatment. Lack of efficacy was suspected because the pet remained presenting fleas and due to this on 2 Aug 2019 he received FRONTLINE PLUS (unsubstantiated) (FL PLUS) (lot, exp date, route and location are unknown) for the first time, but live fleas continue to be seen on the animal. According to the reporter,

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 35 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00042

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Route: Topical / Cutaneous Was the product used ok?: Yes					'the dog has been bathed (on date not informed) but the flea infestation persists'. This is the extent of the information available for now. UPDATE 16 Aug 2019 – The pet owner was contacted and reported that Lost, a male crossbred dog of 1 year old and 16 kg, received one pipette of FRONTLINE SPOT-ON DOGS M (FL) (lot and exp date are still unknown, topical, btw the shoulder blades) for the first time on 26 Jul 2019. On 2 Aug 2019 one pipette of FRONTLINE PLUS DOGS M (FL PLUS) (lot and exp date are still unknown, topical, btw the shoulder blades) was applied because on 29 Jul 2019 live fleas returned to be seen. Lack of efficacy is still suspected because the animal remains with live fleas. FL PLUS has been administered only once in the past (date not informed), with no issue. Environment not treated. No further information is available.
13-Aug-2019	UAE; 19BR003673; SP; Brazil	Species: Feline Breed: Domestic Longhair (Crossbreed) Sex: M Sex qualifier: Unknown Age: 3.50 Year(s) Weight: 13 kg	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	02-Apr-2019	02-Jul-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Bruno, a male Domestic Longhair cat (crossbred) of 3.5 years old and 13 kg, received one pipette of FRONTLINE SPOT-ON CATS (FL) (016/18A, May 2020, topical, btw the shoulder blades and back; the neck's coat was shorn prior to the application) administered by the reporter on 2 Jul 2019 for flea treatment. Lack of efficacy was suspected because the pet remained presenting fleas and due to this on 1 Aug 2019 he was treated with another FL pipette (same presentation, lot, exp date, route and location) but live fleas continue to be seen on the animal. FL has been applied only once in the past (2 Apr 2019) with no issue. There are 9 other cats in the same household that don't have fleas but were treated with FL SPRAY on 24 Jul 2019 with no issue. Environment has not been treated. No further information is available for now.
15-Aug-2019	UAE; 19BR003675; PR; Brazil	Species: Canine Breed: Poodle (Miniature) Sex: M Sex qualifier: Unknown Age: 12.00 Year(s) Weight: 3 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	03-Aug-2019	03-Aug-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, one Poodle of unknown signalment received FRONTLINE (unsubstantiated) (FL) (lot, exp date, route and location are unknown) administered by the reporter on Aug 2019* for an unknown reason. The reporter contacted BIAH because the product was not effective. According to the owner, 'the product was not expired'. This is the extent of the information available for now. UPDATE 22 AUG 2019 – The pet owner informed that Jack, a male Poodle of 12 years old and 3 kg, received FRONTLINE PLUS DOG S (FL) (019/18A, exp date unknown, topical, from neck to tail), administered by the reporter on 3 Aug 2019 for flea treatment. The dog started presenting fleas approximately 1 week prior to FL. Lack of efficacy is suspected because the pet remains with fleas and itching intensely. The owner visualizes live fleas and flea feces on Jack. FL was used in the past with no issue (dose frequency – 4 months, date of first administration was not provided – 2016*). The dog is bathed every 2 months at the pet shop. The neighbor's cat has access to this house. The environment has not been treated. Related case reported on 18BR003753. No further information is available.
15-Aug-2019	UAE; 19BR003678; SP; Brazil	Species: Canine Breed: Shih Tzu Sex: M Sex qualifier: Unknown Age: 1.50 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used:	12-Aug-2019	12-Aug-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via veterinarian, one male Shih Tzu of 1.5 years old received NEXGARD (NG) (unsubstantiated) (lot and exp date unknown), administered orally by the pet owner on 25 Jul 2019 for tick treatment. Lack of efficacy is suspected because she found one tick on her pet on 12 Aug 2019, so FRONTLINE PLUS (FL) (unsubstantiated) (lot, exp date, route and application site

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 36 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00043

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						AFOXOLANER 11.3 MG CHEWABLE TABLETS; Route: unknown Was the product used ok?: Unknown to Company					unknown) was administered to the dog. The veterinarian prescribed environmental treatment with Butox® but it is unknown if the environment was actually treated after that. On 15 Aug 2019 another tick was found on the pet. This is the extent of the information available.
13-Aug-2019	UAE; 19BR003680; RJ; Brazil	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: F Sex qualifier: Unknown Age: 5.00 Year(s) Weight: 4 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: Capstar®; Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	09-Aug-2019	13-Aug-2019*	4 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Mia, a female Domestic Shorthair cat (crossbred) of 5 years old and 4 kg, received one pipette of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical – application on neck, head, base of skull, back and tail – off label use) administered by the reporter on 9 Aug 2019 for flea treatment. Lack of efficacy is suspected because since approx. 13 Aug 2019* live fleas returned to be seen on the cat. Capstar® has been administered before FL application, on approx. 29 Jul 2019*, and 'it has not been effective either'. FL has been administered in the past (dose frequency approx. every 1 or 2 months; estimated last administration date is 9 Jun 2019*). First product's administration date is unknown (confounding information provided; 2016* - estimated). FL SPRAY has been applied 4 months ago (Apr 2019*) with no issue. According to the owner, the cat has no outdoor access, but a dog that lives in the same household uses to be frequently taken for walking outdoors. Environment not treated. Related cases reported on 19BR003681 to 19BR003683. No further information is available. UPDATE 27 Aug 2019 – The pet owner was contacted and reported that 1 week ago the environment has been treated with Butox®. Live fleas are still being found on the pet and lack of efficacy is still suspected due to this. No further information is available.
13-Aug-2019	UAE; 19BR003681; RJ; Brazil	Species: Canine Breed: Retriever (Labrador, Chocolate) Sex: F Sex qualifier: Unknown Age: 8.50 Year(s) Weight: 40 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: Capstar®; Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	09-Aug-2019	13-Aug-2019*	4 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Lola, a female Labrador Retriever of approx. 8.5 years old and 40 kg, received one pipette of FRONTLINE SPOT-ON DOGS L (FL) (lot and exp date are unknown, topical – application on neck, head, base of skull, back and tail – off label use) administered by the reporter on 9 Aug 2019 for flea treatment. Lack of efficacy is suspected because since approx. 13 Aug 2019* live fleas returned to be seen on the dog. Capstar® has been administered before FL application, on approx. 29 Jul 2019*, and 'it has not been effective either'. FL has been administered in the past (dose frequency approx. every 1 or 2 months; estimated last administration date is 9 Jun 2019*) since unknown date (confounding information provided; 2016* - estimated). FL SPRAY has been applied 4 months ago (Apr 2019*) and an AE occurred at the occasion (see 19BR003683). Lola use to be frequently taken for walking outdoors. Environment not treated. Related cases reported on 19BR003680 and 19BR003682. No further information is available. UPDATE 27 Aug 2019 – The pet owner was contacted and reported that 1 week ago the environment has been treated with Butox®. Live fleas are still being found on the pet and lack of efficacy is still suspected due to this. No further information is available.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 37 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

v1.2

ED_005739D_00014390-00044

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
13-Aug-2019	UAE; 19BR003682; RJ; Brazil	Species: Canine Breed: Pinscher (Miniature) Sex: F Sex qualifier: Unknown Age: 4.00 Year(s) Weight: 1 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: Capstar®; Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	09-Aug-2019	13-Aug-2019*	4 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Baby, a female Pinscher of 4 years old and 1 kg, received one pipette of FRONTLINE SPOT-ON DOGS S (FL) (lot and exp date are unknown, topical – application on neck, head, base of skull, back and tail – off label use) administered by the reporter on 9 Aug 2019 for flea treatment. Lack of efficacy is suspected because since approx. 13 Aug 2019* live fleas returned to be seen on the dog. Capstar® has been administered before FL application, on approx. 29 Jul 2019*, and 'it has not been effective either'. FL has been administered in the past (dose frequency approx. every 1 or 2 months; estimated last administration date is 9 Jun 2019*) since unknown date (confounding information provided; 2016* - estimated). FL SPRAY has been applied 4 months ago (Apr 2019*) and an AE occurred at the occasion (see 19BR003683). According to the owner, the dog has no outdoor access but there is another dog that lives in the same household that uses to be frequently taken for walking outdoors. Environment not treated. Related cases reported on 19BR003680 and 19BR003681. No further information is available. UPDATE 27 Aug 2019 – The pet owner was contacted and reported that 1 week ago the environment has been treated with Butox®. Live fleas are still being found on the pet and lack of efficacy is still suspected due to this. No further information is available.
15-Aug-2019	UAE; 19BR003683; RJ; Brazil	Species: Bovine Breed: - Sex: F Sex qualifier: Unknown Age: 4.00 Year(s) Weight: 1 - 40 kg	2	2	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	Apr-2019	Apr-2019	0 Day(s)	D-D	Suspected Adverse Event: As reported by the pet owner, 2 female dogs (Lola, Labrador Retriever, approx. 8 years old and 40 kg; Baby, Pischer, 4 years old and 1 kg) received FRONTLINE SPRAY (FL) (unsubstantiated; lot, exp date, route and location are unknown) for the first time, administered by the reporter on Apr 2019 for flea treatment. It is unknown if prior to the application both dogs were in good health. Approx. 6 hours post FL administration, they experienced vomiting and diarrhea and recovered an unknown time later. It was not informed whether they have been taken to the DVM or if any treatment has been provided. Related cases reported on 19BR003680 to 19BR003682. This is the extent of the information available.
14-Aug-2019	UAE; 19BR003689; -; Brazil	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	01-Aug-2019*	01-Aug-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, one dog of unknown signalment received FRONTLINE SPRAY (FL) (lot, exp date, route and application site unknown), administered by the reporter on date not informed (1 Aug 2019*) for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The environment has been treated with Butox®. This is the extent of the information available.
15-Aug-2019	UAE; 19BR003691; -; Brazil	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	3	3	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous	01-Aug-2019*	01-Aug-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 3 cats of unknown signalment received 1 dose of FRONTLINE PLUS CATS (FL) (lot and exp date unknown, topical, btw the shoulder blades) each, for the first time, administered by the reporter on date not informed (1 Aug 2019*) for flea treatment. Lack of efficacy is suspected because the pets remain with fleas. The owner lives next to a valley and believes that the fleas are coming from rats and skunks that live in the region. There is a dog that lives in this house and it is unknown if it was treated and if it has fleas. The environment has not been treated. This is the extent

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 38 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00045

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Was the product used ok?: Yes					of the information available.
16-Aug-2019	UAE; 19BR003698; SP; Brazil	Species: Feline Breed: Feline various breeds Sex: X Sex qualifier: Unknown Age: 4.90 Year(s) Weight: 3.5 - 5 kg	5	5	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	05-May-2019*	05-May-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pets owner, 5 cats (3 male Persians, 1 male crossbred and 1 female crossbred of approximately 4.9 to 8 years old and 3.5 to 5 kg) received 1 dose of FRONTLINE PLUS CATS (FL) (005/18A, exp date unknown, topical, btw the shoulder blades) each, for the first time, administered by the reporter in early May (5 May 2019*) for flea treatment. Another administration of FL was made in early June (5 Jun 2019*). Lack of efficacy is suspected because the cats remained with fleas, so Revolution® was administered on date not informed (5 Jul 2019*) and no more fleas were visualized. The environment was treated by a specialized company while the cats were at the owner's father's country house. Two cats presented AEs after FL, so SAE cases were reported on 19BR003699 and 19BR003700. No further information is available.
16-Aug-2019	UAE; 19BR003699; SP; Brazil	Species: Feline Breed: Persian (No Further Description) Sex: M Sex qualifier: Unknown Age: 8.00 Year(s) Weight: 4 kg	5	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	05-May-2019*	07-May-2019*	2 Day(s)	D-D	Suspected Adverse Event: As reported by the pet owner, Piticu, a male Persian of 8 years old and 4 kg, received FRONTLINE PLUS CATS (FL) (005/18A, exp date unknown, topical, btw the shoulder blades) for the first time, administered by the reporter in early May (5 May 2019*) for flea treatment. The cat was in good health prior to FL. Some time after product administration the animal presented hair loss at the application site. The cat recovered spontaneously on date not informed (20 May 2019*). There are 4 other cats that were treated with FL on the same date with no issue living in this household. Related cases reported on 19BR003698 and 19BR003700. No further information is available.
16-Aug-2019	UAE; 19BR003700; SP; Brazil	Species: Feline Breed: Persian (No Further Description) Sex: M Sex qualifier: Unknown Age: 7.00 Year(s) Weight: 5 kg	5	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	05-Jun-2019*	07-Jun-2019*	2 Day(s)	D-D	Suspected Adverse Event: As reported by the pet owner, Chico, a male Persian of 7 years old and 5 kg, received FRONTLINE PLUS CATS (FL) (005/18A, exp date unknown, topical, btw the shoulder blades), administered by the reporter in early June (5 Jun 2019*) for flea treatment. The cat was in good health prior to FL. Some time after product administration the animal presented brittle hair at the application site. The cat recovered spontaneously on date not informed (20 Jun 2019*). FL was used once approximately one month earlier (5 May 2019*) with no issue. There are 4 other cats that were treated with FL on the same date with no issue living in this household. Related cases reported on 19BR003698 and 19BR003699. No further information is available.
16-Aug-2019	UAE; 19BR003704; SP; Brazil	Species: Feline Breed: Feline various breeds Sex: M Sex qualifier: Unknown Age: 15.00 Year(s) Weight: 3.5 - 4 kg	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	12-Aug-2019	12-Aug-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pets owner, 2 cats of unknown signalment received FRONTLINE PLUS CATS (FL) (lot, exp date, route and application site unknown), administered by the reporter on 12 Aug 2019 for flea treatment. Lack of efficacy is suspected because the pets remain with fleas. This is the extent of the information available. UPDATE 21 Aug 2019 – The pet owner was contacted and reported that 2 male cats (Floquinho, Turkish Angora, 16 years old, 3.5 kg; Frajola, Domestic Shorthair (crossbred), 15 years old, 4 kg) received one pipette of FL (topical, btw the shoulder blades) each, on 12 Aug 2019 for flea treatment. Live fleas are still being found on both animals. FL has been applied in the past (dose frequency and 1st administration

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 39 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00046

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						ok?: Yes					date are unknown) with no issue. According to the reporter, 'she has used FRONTLINE (unsubstantiated) once in the past and it didn't work either', however, details regarding this event and valid patient info have not been provided. Environment not treated. No further information is available.
19-Aug-2019	UAE; 19BR003706; SP; Brazil	Species: Canine Breed: Rottweiler Sex: F Sex qualifier: Unknown Age: 1.40 Year(s) Weight: 35 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	16-Aug-2019	16-Aug-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Kiara, a female Rottweiler of 1.4 years old and 35 kg, received one pipette of FRONTLINE SPOT-ON DOGS L (FL) (020/18A, exp date is unknown, topical, btw the shoulder blades) for the first time, administered by the reporter on 16 Aug 2019 for flea and tick treatment. Lack of efficacy is suspected because live fleas and ticks are still being seen on the dog. According to the reporter, ticks are appearing in greater quantity than fleas. Environment has been partially treated (only the house's floor). No further information is available.
19-Aug-2019	UAE; 19BR003708; RJ; Brazil	Species: Canine Breed: Poodle (Toy) Sex: X Sex qualifier: Unknown Age: 9.00 Month(s) Weight: 8 - 9 kg	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	17-Aug-2019	17-Aug-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pets owner, 2 Poodles (Thor, male of 9 months old and 9 kg; Luna, female of 9 months old and 8 kg) received 1 dose of FRONTLINE PLUS DOG S (007/18A and 022/18A, exp date unknown, topical, btw the shoulder blades) each, administered by the reporter on 17 Aug 2019 for flea and tick treatment. The dogs started presenting ectoparasites 1 month prior to FL. Lack of efficacy is suspected because the pets remain with fleas and small ticks, in moderate quantity. 2 big ticks were removed from Thor. FL was used in the past with no issue (dose frequency is unknown and date of first administration was not provided - Mar 2019*). The animals are bathed weekly. The environment has been treated with Triatox®. Related case reported on 19BR003709. No further information is available.
19-Aug-2019	UAE; 19BR003709; RJ; Brazil	Species: Canine Breed: Beagle Sex: F Sex qualifier: Unknown Age: 13.00 Year(s) Weight: 13 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	17-Aug-2019	17-Aug-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Nina, a female Beagle of 13 years old and 13 kg, received 1 dose of FRONTLINE PLUS DOG M (013/18A, exp date unknown, topical, btw the shoulder blades), administered by the reporter on 17 Aug 2019 for flea and tick treatment. The dog started presenting ectoparasites 1 month prior to FL. Lack of efficacy is suspected because the pet remains with fleas and small ticks, in moderate quantity. FL was used in the past with no issue (dose frequency is unknown and date of first administration was not provided - 2018*). The animal is bathed weekly. The environment has been treated with Triatox®. Related case reported on 19BR003708. No further information is available.
19-Aug-2019	UAE; 19BR003710; SP; Brazil	Species: Canine Breed: Yorkshire Terrier Sex: X Sex qualifier: Unknown Age: 9.00 Month(s) Weight: 2 - 5 kg	2	2	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	04-Aug-2019	04-Aug-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pets owner, 2 Yorkshire Terriers (Scay, female of 9 months old and 2 kg; Bob, male of 10 years old and 5 kg) received 1 dose of FRONTLINE SPOT-ON DOGS S (010/18B and 011/18B, exp date unknown, topical, btw the shoulder blades) each, administered by the reporter on 4 Aug 2019 for flea treatment. The animals started presenting fleas after a walk approximately 2 weeks prior to FL. Lack of efficacy is suspected because the pets continue to itch and remain with fleas, although in smaller quantity than before treatment. FL was used in the past with no issue (dose frequency - 6 months, date of first administration was not provided). The environment was treated once with unknown product. Related

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
 Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
 *indicates Approximate date or weight

Page 40 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).
 Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.
 Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00047

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											case reported on 19BR003711. No further information is available.
19-Aug-2019	UAE; 19BR003711; SP; Brazil	Species: Canine Breed: Canine various breeds Sex: X Sex qualifier: Unknown Age: 9.00 Year(s) Weight: 10 - 15 kg	2	2	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	04-Aug-2019	04-Aug-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pets owner, 2 dogs (Lara, female Labrador of 14 years old and 15 kg; Herus, male of 9 years old and 10 kg) received 1 dose of FRONTLINE SPOT-ON DOGS M (024/17A, exp date unknown, topical, btw the shoulder blades) each, administered by the reporter on 4 Aug 2019 for flea treatment. The animals started presenting fleas after a walk approximately 2 weeks prior to FL. Lack of efficacy is suspected because the pets continue to itch and remain with fleas, although in smaller quantity than before treatment. FL was used in the past with no issue (dose frequency - 6 months, date of first administration was not provided). The environment was treated once with unknown product. Related case reported on 19BR003710. No further information is available.
17-Aug-2019	UAE; 19BR003723; SP; Brazil	Species: Feline Breed: Persian (No Further Description) Sex: M Sex qualifier: Unknown Age: 7.00 Year(s) Weight: 3.5 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	05-Jul-2019	23-Jul-2019*	18 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Pedrinho, a male longhair Persian cat of 7 years old and approx. 3.5 kg, received one pipette of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades) for the first time, administered by the reporter on 5 Jul 2019 for ectoparasite prevention. Lack of efficacy is suspected because since approx. 23 Jul 2019 live fleas started to be seen on Pedrinho. According to the reporter, the cat has flea allergy dermatitis and due to the flea infestation he is experiencing allergy. Pedrinho use to be bathed every 15 days. Environment has not been treated. No further information is available.
18-Aug-2019	UAE; 19BR003731; -, Brazil	Species: Feline Breed: Feline (unknown) Sex: X Sex qualifier: Unknown Age: 2.00 Month(s) Weight: 1.7 kg	2	2	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	Jul-2019	Jul-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, 2 cats of 2 months old and unknown signalment received FRONTLINE SPRAY (FL SPRAY) (unsubstantiated; lot and exp date are unknown, topical, whole body) administered by the reporter on date not informed (Aug 2019*) for flea treatment. Lack of efficacy is suspected because the cats remain with live fleas. This is the extent of the information available for now. UPDATE 22 Aug 2019 – The pet owner was contacted and reported that 1 cat is female and the other one is male, both have 2 months old and approx. 1.7 kg. Both cats received FL SPRAY 100 ML (topical, whole body) on Jul 2019. Another ectoparasiticide product (unknown) was administered for treatment, however, it was not informed if fleas are still being found. Environment not treated. One picture of the FL bottle was received. No further information is available.
20-Aug-2019	UAE; 19BR003732; SP; Brazil	Species: Canine Breed: Yorkshire Terrier Sex: F Sex qualifier: Unknown Age: 11.00 Month(s) Weight: 1.7 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	19-Aug-2019	20-Aug-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Nicole, a female Yorkshire of 11 months old and 1.7 kg, received FRONTLINE PLUS DOG S (011/18A, exp date unknown, topical, btw the shoulder blades), administered by the reporter on 19 Aug 2019 for flea treatment. The dog started presenting fleas approximately 3 weeks prior to FL. Lack of efficacy is suspected because she visualized a few fleas walking on the dog's belly approximately 10 hours after product administration. FL was used twice in the past with no issue (20 Feb 2019* and 25 May 2019* - dates are estimated). Nicole is bathed every 15 days (once a month at the pet shop) and goes out for walks every 3 days. The environment has been treated with Butox®. No further information is available.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
 Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
 *indicates Approximate date or weight

Page 41 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00048

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
20-Aug-2019	UAE; 19BR003740; SP; Brazil	Species: Feline Breed: Feline various breeds Sex: M Sex qualifier: Unknown Age: 4.00 Month(s) Weight: 1.6 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Indication not indicated / recommended)	19-Aug-2019	19-Aug-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Raji, a male crossbred cat of 4 months old and 1.6 kg, received 1 dose of FRONTLINE PLUS CATS (lot and exp date unknown, topical, btw the shoulder blades) for the first time, administered by the reporter on 19 Aug 2019 for itch treatment. Lack of efficacy is suspected because the pet is still itching. No ectoparasites were visualized before or after product administration. The environment is treated yearly by a specialized company. No further information is available.
20-Aug-2019	UAE; 19BR003742; -; Brazil	Species: Canine Breed: Canine (unknown) Sex: F Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	20-May-2019*	20-May-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, one female dog of unknown signalment received FRONTLINE PLUS DOG S (lot, exp date, route and application site unknown), administered by the reporter 3 months ago (20 May 2019*) for unknown reason. Lack of efficacy is suspected. FL was used in the past with no issue (dose frequency is unknown and date of first administration was not provided). Related case reported on 19BR003743. This is the extent of the information available.
20-Aug-2019	UAE; 19BR003743; -; Brazil	Species: Canine Breed: Canine (unknown) Sex: F Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	15-Aug-2019*	15-Aug-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, one female dog of unknown signalment received FRONTLINE PLUS DOG S (lot, exp date, route and application site unknown), administered by the reporter last week (15 Aug 2019*). Lack of efficacy is suspected because one live tick was visualized on the pet after product administration. It is unknown if the dog still has ticks. FL was used in the past with no issue (dose frequency is unknown and date of first administration was not provided), however lack of efficacy is also suspected for the previous administration (see case 19BR003742). This is the extent of the information available.
20-Aug-2019	UAE; 19BR003745; RJ; Brazil	Species: Canine Breed: Poodle (Toy) Sex: X Sex qualifier: Unknown Age: 2.00 Year(s) Weight: 3 - 6 kg	4	4	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination	18-Aug-2019	18-Aug-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pets owner, 4 Poodles (2 males and 2 females) of 2 to 12 years old and 3 to 6 kg received FRONTLINE SPRAY (FL) (lot and exp date unknown, topical, from neck to tail, legs), administered by the reporter on dates not informed (number of administrations is unknown - Jul 2019* to 18 Aug 2019) for flea treatment. The dogs started presenting fleas on the same date of the first administration of FL. Lack of efficacy is suspected because the pets remain with fleas. The dogs are bathed weekly. FL was used in the past with no issue (dose frequency is unknown and date of first administration was not provided). The environment has been treated with Butox®. No further information is available.

N/A signifies the information for this field is either not available or not applicable

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

Report printed on 25-Oct-2019 at 8:39:59PM

*indicates Approximate date or weight

Page 42 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00049

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						program not respected)					
20-Aug-2019	UAE; 19BR003749; ES; Brazil	Species: Canine Breed: Retriever (Golden) Sex: F Sex qualifier: Unknown Age: 3.00 Month(s) Weight: 3 kg	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	12-Aug-2019*	12-Aug-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Suzy, a female Golden Retriever of 3 months old and 3 kg, received FRONTLINE SPRAY (FL) (003/18A, exp date unknown, topical, neck/armpits/ears/head) for the first time, administered by the reporter's wife last week (12 Aug 2019*) for tick treatment. The dog presented 3 or 4 ticks 1 day prior to FL. Lack of efficacy is suspected because the pet remained with ticks, so another application of FL was made (whole body) on date not specified (15 Aug 2019*) and the pet still has live ticks. He usually visualizes 2 or 3 ticks and removes them, and some time later new ticks are visualized. There are 2 dogs treated with unknown oral product living in this household and they do not have ticks. The environment has not been treated. No further information is available.
22-Aug-2019	UAE; 19BR003753; PR; Brazil	Species: Canine Breed: Pit Bull Sex: M Sex qualifier: Unknown Age: 11.00 Year(s) Weight: 20 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	03-Aug-2019	03-Aug-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Hancock, a male Pit Bull of 11 years old and 20 kg, received FRONTLINE PLUS DOGS (FL) (unsubstantiated) (020/18A, exp date unknown, topical, from neck to tail), administered by the reporter on 3 Aug 2019 for flea treatment. The dog started presenting fleas approximately 1 week prior to FL. Lack of efficacy is suspected because the pet remains with fleas. FL was used in the past with no issue (dose frequency – 4 months, date of first administration was not provided – 2016*). The dog is bathed weekly at home. The neighbor's cat has access to this house. The environment has not been treated. Related case reported on 18BR003675. No further information is available.
22-Aug-2019	UAE; 19BR003764; SP; Brazil	Species: Feline Breed: Feline various breeds Sex: M Sex qualifier: Unknown Age: 10.00 Year(s) Weight: 3.5 kg	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	12-Aug-2019	13-Aug-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pets owner, Trovão Loirinho and Fredy, 2 male crossbred cats of 10 to 11 years old and approximately 3.5 kg received 1 dose of FRONTLINE PLUS CATS (FL) (002/18B, exp date unknown, topical, btw the shoulder blades) each, administered by the reporter on 12 Aug 2019 for flea and tick prevention. The cats were itching but did not present fleas prior to FL. Lack of efficacy is suspected because the reporter visualizes flea feces on the pets. One dead flea was visualized on the bed one day after product administration. FL was used in the past with no issue (dose frequency - 3 to 4 months, date of first administration was not provided - 2010*). There are 2 treated dogs with no fleas living in this house. The environment has not been treated. The reporter states that he perceived a difference in the viscosity of the product, so TPC case was reported on GOTrack (PRID 482279). No further information is available. 20-SEP-19 QA results received: Investigation completed for FIPRONIL 10%/S METHOPRENE 12% SPOT ON Lot# 002/18B, expiry 2019-12-31. Case investigated by France - Toulouse. Final complaint evaluation A TPC was received for frontline plus Cat, batch 002/18, on 23/08/19. The defect is : product abnormal consistency . Recurrence : this is the first complaint for this kind of defect (regarding this batch) Batch record

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 43 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00050

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											review : S402 Bulk batch : 999 liters manufactured on 24/01/2018 ; results of QC testing are conform including product density S40218 Filling batch : 56000 pipettes manufactured on 28/02/2018 (expiry 12/21). Results of QC testing are conform. 10 IPC (= 120 pipettes) were performed (including volume control and tightness) and were conform No deviations nor change control associated to the defect. Root cause : No explanation was found about this problem. The product is very stable in normal storage conditions. Punctually, the product can be gelatinous, crystallized or not oily as usual . It could be due to
22-Aug-2019	UAE; 19BR003778; SP; Brazil	Species: Canine Breed: Maltese Sex: F Sex qualifier: Unknown Age: 7.00 Month(s) Weight: 3 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-Aug-2019	01-Aug-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Mel, a female Maltese of 7 years old and 3 kg, received one pipette of FRONTLINE SPOT-ON DOGS S (FL) (019/18A, exp date is unknown, topical, btw the shoulder blades), administered by the reporter on 1 Aug 2019 for flea treatment. Lack of efficacy is suspected because live fleas are still being found on Mel. FL has been administered only once in the past (last year - 2018, date not informed) with no issue. The dog use to be bathed every 2 months on a pet store. There are 2 dogs that live in the same household and they have not been simultaneously treated. Environment has not been treated as well. No further information is available.
23-Aug-2019	UAE; 19BR003789; RS; Brazil	Species: Canine Breed: Medium crossbred (10 - 20 Kg) Sex: M Sex qualifier: Unknown Age: 3.00 Year(s) Weight: 19.8 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	08-Aug-2019	23-Aug-2019	15 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Bob, a male medium crossbred dog of 3 years old and approximately 19.8 kg, received FRONTLINE PLUS DOG M (lot and exp date unknown, topical, btw the shoulder blades), administered by the reporter on 8 Aug 2019 for tick treatment. The dog started presenting ticks on late July 2019. Lack of efficacy is suspected because she found 2 live ticks attached to her pet on 23 Aug 2019. She removed them and no more ticks were visualized so far. This dog rarely has access to the street. FL was used once over 1 year ago with no issue (Jun 2018*). The environment has been treated with K-Othrine® and Barrage®. No further information is available.
23-Aug-2019	UAE; 19BR003790; SP; Brazil	Species: Canine Breed: Canine various breeds Sex: F Sex qualifier: Unknown Age: 3.00 Year(s) Weight: 3 - 7 kg	3	3	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	03-Aug-2019	03-Aug-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pets owner, 3 female dogs (Mel, Yorkshire of 8 years old and 3 kg; Clara, small crossbred of 3 years old and 7 kg; Juma, Maltese of 3 years old and 5 kg) received FRONTLINE SPRAY (FL) (lot and exp date unknown, topical, whole body), administered by the reporter on 3 Aug 2019 for flea treatment. They were bathed in the morning and FL was administered in the afternoon. The dogs started presenting fleas 1.5 weeks prior to FL. Lack of efficacy is suspected because the pets remain with fleas. The dogs are bathed every 15 days. FL was used in the past with no issue (dose frequency is unknown and date of first administration was not provided - 2017*). The environment has not been treated. No further information is available.
23-Aug-2019	UAE; 19BR003791; RJ; Brazil	Species: Feline Breed: Feline various breeds Sex: X Sex qualifier: Unknown Age: 6.00 Month(s)	3	3	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous	01-Aug-2019*	Jun-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pets owner via BI employee, 3 crossbred cats (Miguel, male; Sara and Serena, females) of approximately 6 months old and approximately 1 kg received FRONTLINE SPRAY (FL) (002/18B, exp date Jun 2020, topical, whole body), administered by the reporter on date not informed (1 Aug 2019*) for flea treatment. Lack of efficacy is suspected because the pets remained with fleas, so another administration of FL was made less than one month later (22 Aug

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 44 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00051

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: 1 kg*				Was the product used ok?: No (Treatment / vaccination program not respected)					2019*). The cats remain with fleas. The reporter says that she used FL in the past with no issue (it is unknown if these animals were treated before) and believes there is a problem with this batch. The environment has been treated with unknown product. No further information is available. UPDATE 25 Sep 2019 – The pet owner informed that FL was applied on Jun 2019 and fleas were no longer found on the cats after an unknown ectoparasiticide product was administered on date not informed (Sep 2019*). Environment has been treated with K-Othrine®. She informed that multiple costumers are complaining about FL, however, no patient and event info has been provided. No further information is available.
20-Aug-2019	UAE; 19BR003801; -; Brazil	Species: Canine Breed: Medium crossbred (10 - 20 Kg) Sex: F Sex qualifier: Unknown Age: 2.50 Year(s) Weight: 11.5 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	03-Aug-2019*	03-Aug-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, one female crossbred dog of approximately 11.5 kg received FRONTLINE (FL) (unsubstantiated) (lot, exp date, route and application site unknown), administered by the reporter on date not informed (10 Aug 2019*) for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The same issue occurred after a previous administration (date not provided). This is the extent of the information available. UPDATE 3 SEP 2019 – The pet owner informed that Sofia, a female medium crossbred dog of approximately 2.5 years old and approximately 11.5 kg, received FRONTLINE PLUS (unsubstantiated) approximately 1 month ago (3 Aug 2019*). The pet remains with fleas. FL was used once 1.3 years ago with the same issue (Apr 2018*). Sofia goes out for walks daily. There is an untreated dog living in this house. The environment has not been treated. No further information is available.
26-Aug-2019	UAE; 19BR003811; RJ; Brazil	Species: Feline Breed: Feline various breeds Sex: X Sex qualifier: Unknown Age: 4.00 Year(s) Weight: 3 - 4.8 kg	2	2	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	03-Aug-2019	03-Aug-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pets owner, 2 crossbred cats (Oncinha, female of 4 years old and 3 kg; Tutu, male of 7 years old and approximately 4.8 kg) received FRONTLINE SPRAY (FL) (002/18B, exp date unknown, topical, neck, belly and tail), administered by the reporter on 3 Aug 2019 for flea treatment. The pets started presenting fleas over a month prior to FL. Lack of efficacy is suspected because the pets remained with fleas, so another application of FL was made on 19 Aug 2019. The owner continues to visualize small fleas, big fleas and flea feces on the animals. FL was used in the past (dose frequency is unknown and date of first administration was not provided). The environment has not been treated. Related case reported on 19BR003812. No further information is available.
26-Aug-2019	UAE; 19BR003812; RJ; Brazil	Species: Canine Breed: Rottweiler Sex: M Sex qualifier: Unknown Age: 8.00 Year(s) Weight: 50 kg*	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination	03-Aug-2019	03-Aug-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Rotinho, a male Rottweiler of 8 years old and 50 kg, received FRONTLINE SPRAY (FL) (002/18B, exp date unknown, topical, from neck to tail, belly and legs), administered by the reporter on 3 Aug 2019 for flea treatment. The pet started presenting fleas over a month prior to FL. Lack of efficacy is suspected because the pets remained with fleas, so another application of FL was made on 19 Aug 2019. The owner continues to visualize small fleas, big fleas and flea feces on the animal. FL was used in the past (dose frequency is unknown and date of first administration was not provided). The environment has not been treated. Related case reported on 19BR003811. No further information is available.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 45 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00052

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						program not respected)					
26-Aug-2019	UAE; 19BR003819; DF; Brazil	Species: Canine Breed: Shih Tzu Sex: M Sex qualifier: Unknown Age: 3.00 Month(s) Weight: 2.2 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	14-Aug-2019	14-Aug-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Neném, a male Shih Tzu of 3 months old and 2.2 kg, received one pipette of FRONTLINE PLUS DOGS S (FL) (lot and exp date are unknown, topical, btw the shoulder blades) for the first time, administered by the reporter on approx. 14 Aug 2019 for tick treatment. Lack of efficacy is suspected because every day live around 2-3 ticks are being found on the dog. Whenever the ticks are visualized they are manually removed by the pet owner. On 25 Aug 2019 one live flea was also found on the pet but it was no longer seen. Neném use to be bathed every 8 days. There is 1 dog living in the same household that has been treated with Simparic®. Environment treated with Triatox® and Poderoso®. No further information is available.
26-Aug-2019	UAE; 19BR003823; SP; Brazil	Species: Canine Breed: Small crossbred (<10 Kg) Sex: M Sex qualifier: Unknown Age: 12.00 Year(s) Weight: 9 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	Mar-2019*	Mar-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Toddy, a male small crossbred dog of 12 years old and 9 kg, received 1 dose of FRONTLINE SPOT-ON DOGS S (lot and exp date unknown, topical, btw the shoulder blades), administered by the reporter on March 2019 for flea treatment. Lack of efficacy is suspected because the pet remained with fleas, so another application of FL was made on 16 Aug 2019. FL was used in the past with no issue (dose frequency - yearly, date of first administration was not provided). Toddy has not been bathed lately because he has been sick (no details were provided). The environment has been treated with Butox® (frequency was not provided). No further information is available.
26-Aug-2019	UAE; 19BR003825; SP; Brazil	Species: Feline Breed: Feline various breeds Sex: M Sex qualifier: Unknown Age: 2.00 Year(s) Weight: 2.9 - 7 kg	2	2	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	23-Aug-2019	23-Aug-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 male cats (Sherlock, British Shorthair, 3 years old, 2.9 kg; Watson, Siamese, 2 years old, 7 kg) received one pipette of FRONTLINE SPOT-ON CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades) each, for the first time, administered by the reporter on 23 Aug 2019 for flea treatment. Lack of efficacy is suspected because live fleas are still being found on the cats. According to the reporter, she is not visualizing 'a lot of fleas' but the animals are experiencing intense itching and due to this she suspects that the product has not been effective. Environment has been treated with an unknown product. No further information is available.
26-Aug-2019	UAE; 19BR003831; RJ; Brazil	Species: Canine Breed: French Bulldog Sex: M Sex qualifier: Unknown Age: 2.00 Month(s) Weight: 3.6 kg	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination	04-Aug-2019*	04-Aug-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Pirata, a male French Bulldog of 2 months old and 3.6 kg, received FRONTLINE SPRAY (FL) (002/17, exp date Jun 2020, topical, whole body except head) for the first time, administered by the reporter on date not specified (4 Aug 2019*) for flea treatment. Lack of efficacy is suspected because the pet remained with fleas, so new applications of FL were made every 2 days until 22 Aug 2019. On 24 Aug 2019 one last application of FL was made (whole body) and the dog remains with fleas. There is a dog treated with Bravecto® with no fleas living in this house. The environment was treated with Butox on 23 Aug 2019. During the last application the dog had ocular exposure to the product, so SAE case was reported on 19BR003832. No further information is available.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
 Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
 *indicates Approximate date or weight

Page 46 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00053

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						program not respected)					
26-Aug-2019	UAE; 19BR003832; RJ; Brazil	Species: Canine Breed: French Bulldog Sex: M Sex qualifier: Unknown Age: 2.00 Month(s) Weight: 3.6 kg	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Ophthalmic Was the product used ok?: No (Route not indicated / recommended)	24-Aug-2019	25-Aug-2019*	1 Day(s)	D-C	Suspected Adverse Event: As reported by the pet owner, Pirata, a male French Bulldog of 2 months old and 3.6 kg, received FRONTLINE SPRAY (FL) (002/17, exp date Jun 2020, topical, whole body), administered by the reporter on 24 Aug 2019 for flea treatment. The dog was in good health prior to product administration and received FL (whole body except head) every 2 days from 4 Aug 2019* to 22 Aug 2019 with no issue. During product administration the pet owner accidentally sprayed FL directly on the dog's eyes. Right after ocular exposure she washed his eyes with saline solution. On the next morning the animal presented eyelid edema, conjunctival edema, whitening of the eyes (corneal edema) and exophthalmia. He was taken to the veterinarian and also presented corneal ulceration on the right eye. The owner believes that the dog could have scratched this eye causing the ulceration. Pirata has been treated with Meloxivet®, Reginsel® pomade (BID) and platelet rich plasma. Signals are decreasing. The veterinarian believes that the pressure of the spray caused the signals, not the product itself. There is a dog that was not treated with FL living in this house. SLOE case reported on 19BR003831. No further information is available.
28-Aug-2019	UAE; 19BR003834; SP; Brazil	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: F Sex qualifier: Unknown Age: 35.00 Month(s) Weight: 5.5 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	20-Aug-2019	20-Aug-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Gigi, a female Domestic Shorthair cat (crossbred) of 35 months old and approx. 5.5 kg, received one pipette of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades) for the first time, administered by the reporter on 20 Aug 2019 for flea treatment. Lack of efficacy is suspected because live fleas are still being found on the cat. The number of fleas decreased post product administration, however, they are still seen. According to the reporter, Gigi rarely has outdoor access. Environment treated with an unknown product. No further information is available.
28-Aug-2019	UAE; 19BR003835; SP; Brazil	Species: Canine Breed: Pomeranian Sex: F Sex qualifier: Unknown Age: 7.00 Month(s) Weight: 3.6 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	11-Jun-2019	20-Aug-2019*	10 Week(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Becky, a female Pomeranian of 7 months old and 3.6 kg, received one pipette of FRONTLINE PLUS DOGS S (FL) (lot and exp date are unknown, topical, btw the shoulder blades) for the first time, administered by the reporter on 11 Jun 2019 for ectoparasite prevention. Lack of efficacy is suspected because live fleas are being found on the dog. Before FL, Revolution® used to be administered to Becky but the dose frequency was not informed. Environment not treated. No further information is available.
29-Aug-2019	UAE; 19BR003839; RJ; Brazil	Species: Canine Breed: Poodle (Toy) Sex: F Sex qualifier: Unknown Age: 6.00	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical /	28-Aug-2019	28-Aug-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Perola, a female Poodle of 6 months old and 4.5 kg, received FRONTLINE SPRAY (FL) (002/18, exp date unknown, topical, whole body) for the first time, administered by the reporter on 28 Aug 2019 for tick treatment. The dog started presenting ticks approximately 2 weeks prior to FL. Lack of efficacy is suspected because the pet remains with live ticks. The dog has been bathed

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 47 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00054

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Month(s) Weight: 4.5 kg				Cutaneous Was the product used ok?: Yes					every 15 days and does not have access to the street. There are 3 dogs treated with Bravecto® or NEXGARD living in this household and they do not have ticks anymore. The environment has been treated with Alpha Ciper®. No further information is available.
27-Aug-2019	UAE; 19BR003840; SP; Brazil	Species: Canine Breed: Border Collie Sex: M Sex qualifier: Unknown Age: 4.00 Year(s) Weight: 23 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	23-Aug-2019	23-Aug-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Fred, a male Border Collie of 4 years old and 23 kg, received FRONTLINE PLUS DOG L (lot and exp date unknown, topical, btw the shoulder blades), administered by the reporter on 23 Aug 2019 for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. FL was used in the past with no issue (dose frequency is unknown and date of first administration was not provided), but later he started to use an unknown ectoparasiticide collar on the dog. This is the extent of the information available.
28-Aug-2019	UAE; 19BR003843; MG; Brazil	Species: Canine Breed: Pomeranian Sex: M Sex qualifier: Unknown Age: 7.70 Year(s) Weight: 12 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	2018*	23-Aug-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Lucky, a male Pomeranian of 1.7 years old and 12 kg, received one pippete of FRONTLINE SPOT-ON DOGS M (FL) (024/17A, exp date is unknown, topical, btw the shoulder blades), administered by the reporter on 23 Aug 2019 for flea treatment. Lack of efficacy is suspected because live fleas are still being found on the dog. FL has been administered in the past, every 45 days since date not informed (2018*), with no issue. There are 2 other dogs living in the same household and they have been simultaneously treated with Frontline Spray® - according to the reporter, they don't have fleas. Environment not treated. No further information is available.
29-Aug-2019	UAE; 19BR003845; MG; Brazil	Species: Canine Breed: Shih Tzu Sex: M Sex qualifier: Unknown Age: 6.50 Year(s) Weight: 10 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	10-Aug-2019	20-Aug-2019*	10 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Marley, a male Shih Tzu of 6.5 years old and 10 kg, received FRONTLINE PLUS DOGS M (FL) (lot is unknown, Sep 2019, topical, btw the shoulder blades) administered by the reporter on 10 Aug 2019 for tick treatment. Lack of efficacy is suspected because on approx. 20 Aug 2019* the retail shop staff member found one live tick on the dog. The dog use to be bathed on a pet store. FL has been administered every 3 months, since date not informed (2017*), with no issue. Environment not treated. No further information is available.
21-Aug-2019	UAE; 19BR003846; -; Brazil	Species: Canine Breed: Pit Bull Sex: F Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	06-Aug-2019	21-Aug-2019*	15 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, one female Pit Bull of unknown signalment received FRONTLINE (FL) (unsubstantiated) (lot, exp date, route and application site unknown), administered by the reporter on 6 Aug 2019. Lack of efficacy is suspected because the owner found 3 live ticks on the pet after treatment. FL was used in the past with no issue (dose frequency is unknown and date of first administration was not provided). This is the extent of the information available.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 48 of 867

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00055

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
29-Aug-2019	UAE; 19BR003847; CE; Brazil	Species: Canine Breed: Shih Tzu Sex: M Sex qualifier: Unknown Age: 50.00 Day(s) Weight: 2 kg	2	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	25-Aug-2019	29-Aug-2019*	4 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Baruck, a male Shih Tzu of 50 days old and 2 kg, received one pipette of FRONTLINE SPRAY 250 ML (FL) (003/18C, exp date is unknown, topical, whole body) for the first time, administered by the reporter on 25 Aug 2019 for tick treatment. Lack of efficacy is suspected because since 29 Aug 2019 live ticks returned to be found on the dog. Whenever the ticks are visualized they are manually removed and killed by the pet owner. There is another dog living in the same household and it has been also treated with FL and an unknown product with no issue. Environment treated with an unknown product. No further information is available.
24-Aug-2019	UAE; 19BR003849; -; Brazil	Species: Feline Breed: Siamese Sex: M Sex qualifier: Unknown Age: 1.30 Year(s) Weight: 3 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	14-Aug-2019*	20-Aug-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, one cat of unknown signalment received FRONTLINE (FL) (unsubstantiated) (lot, exp date, route and application site unknown), administered by the reporter on date not informed (20 Aug 2019*) for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. The reporter states that the environment was 'disinfected'. This is the extent of the information available. UPDATE 3 SEP 2019 – The pet owner informed that Snap, a male Siamese of 1.3 years old and 3 kg, received 1 dose of FRONTLINE PLUS (unsubstantiated) (lot and exp date unknown, topical, btw the shoulder blades) approximately 20 days ago (14 Aug 2019*). The cat does not have outdoor access and remains with fleas. The environment has not been treated. No further information is available.
24-Aug-2019	UAE; 19BR003850; -; Brazil	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	3	3	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	20-Aug-2019*	20-Aug-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pets owner, 3 cats of unknown signalment received FRONTLINE (FL) (unsubstantiated) (lot, exp date, route and application site unknown), administered by the reporter on date not informed (20 Aug 2019*) for flea treatment. Lack of efficacy is suspected because the pets remain with fleas. FL was used approximately 6 times in the past with the same issue (dose frequency is unknown and date of first administration was not provided). The cats do not have access to the street. This is the extent of the information available.
29-Aug-2019	UAE; 19BR003851; SP; Brazil	Species: Canine Breed: Pomeranian Sex: M Sex qualifier: Unknown Age: 3.00 Year(s) Weight: 4.5 kg	3	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	30-Aug-2019	30-Aug-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner (which is a veterinarian), one male Pomeranian of unknown signalment received FRONTLINE SPOT-ON DOGS (FL) (unsubstantiated) (lot, exp date, route and application site unknown), administered by the reporter on date not informed (20 Aug 2019*). Lack of efficacy is suspected because the dog has fleas. FL has been used regularly on the dog (dose frequency is unknown and date of first administration was not provided). There are other dogs with no fleas that were also treated with FL living in this household. This is the extent of the information available. UPDATE 23 Sep 2019 – The pet owner contacted BIAH to report that Bono, a male Pomeranian of 3 years old and 4.5 kg, received one pipette of FRONTLINE SPOT-ON DOGS S (FL) on 30 Aug 2019 for ectoparasite control. Lack of efficacy is still suspected because the dog remains with fleas. FL has been administered only once in the past, approx. 4 months ago (May 2019*) with no issue. The reporter informed that, in addition to FL, Pulgoff® has been also administered to the dog, however, the exact date of use was not informed. Bono use to be bathed every 15 days.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 49 of 867

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00056

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											Environment treated with K-Othrine. No further information is available.
29-Aug-2019	UAE; 19BR003852; SP; Brazil	Species: Feline Breed: Feline various breeds Sex: F Sex qualifier: Unknown Age: 5.00 Month(s) Weight: 3 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	25-Aug-2019*	25-Aug-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pets owner, 2 female cats of unknown signalment received 1 dose of FRONTLINE PLUS CATS (FL) (lot, exp date, route and administration site unknown) each, administered by the reporter on date not informed (25 Jul 2019*) for flea treatment. Lack of efficacy is suspected because the pets remain with fleas, apparently in greater quantity than before treatment. FL was used in the past with no issue (dose frequency is unknown and date of first administration was not provided). The cats do not have outdoor access. There are 2 dogs that were treated with FRONTLINE (unsubstantiated) one week earlier living in this apartment. No further information is available. UPDATE 5 SEP 2019 - The owner was contacted and reported that Maia, a female mixed breed cat of 5 months old and 3 kg was treated with FL (topical, btw the shoulder blades). The animal remains with fleas. In addition, she is scratching herself due to fleas. Environment not treated. As mentioned before, FL was applied in the past with no issue. The second cat was recently adopted by the reporter. So, FL was applied for the first time on this other cat, who remains with fleas (see case 19BR003915). The owner also complained that her two dogs received FL and she believes that they have fleas because they are also scratching themselves (see case 19BR003916). No further information is available.
29-Aug-2019	UAE; 19BR003855; MG; Brazil	Species: Canine Breed: Chowchow Sex: F Sex qualifier: Unknown Age: 1.00 Year(s) Weight: 18 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	09-Aug-2019	22-Aug-2019*	13 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Pandora, a female Chow Chow of 1 year old and 18 kg, received 1 dose of FRONTLINE SPOT-ON DOGS M (lot and exp date unknown, topical, btw the shoulder blades) for the first time, administered by the reporter on 9 Aug 2019 for tick treatment. The dog got ticks during his walks 3 or 4 days prior to FL. Lack of efficacy is suspected because he found 5 ticks attached to the pet during the last week. Pandora used to be treated with Bravecto® in the past. The environment was treated with K-Othrine® on the same date of product administration. No further information is available.
28-Aug-2019	UAE; 19BR003856; MG; Brazil	Species: Canine Breed: Shih Tzu Sex: F Sex qualifier: Unknown Age: 70.00 Day(s) Weight: 1.6 kg	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	20-Aug-2019	24-Aug-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Endy, a female Shih Tzu of 70 days old and 1.6 kg, received FRONTLINE SPRAY 250 ML (FL) (004/18, Sep 2020, topical, whole body) for the first time, administered by the reporter on 20 and 27 Aug 2019 for flea treatment. Lack of efficacy is suspected because live fleas are still being found. Environment partially treated (only the house's external area). Due to a defect on the FL bottle, a case was reported on GoTrack (PRID 486670). No further information is available.
28-Aug-2019	UAE; 19BR003858; RS; Brazil	Species: Feline Breed: Feline various breeds Sex: F Sex qualifier: Unknown Age: 6.00 Month(s)	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous	06-Aug-2019	28-Aug-2019*	22 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, one female cat of unknown signalment received FRONTLINE SPOT-ON CAT (FL) (lot, exp date, route and application site unknown), administered by the reporter on 6 Aug 2019 for flea treatment. The quantity of fleas decreased greatly after treatment. Lack of efficacy is suspected because on 28 Aug 2019 the quantity of fleas on the cat is even greater than before treatment. The cat does not have access to the street. This is the extent of the

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 50 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00057

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: 2.5 kg				Was the product used ok?: Yes					information available. UPDATE 6 SEP 2019 - Vanda, a female mixed breed cat of 6 months old and 2.5 kg, received, for the first time, one vial of FL. The pet remains with fleas. Environment not treated. No further information is expected.
30-Aug-2019	UAE; 19BR003865; MG; Brazil	Species: Canine Breed: American Bully Sex: F Sex qualifier: Unknown Age: 2.00 Year(s) Weight: 18 - 25 kg	3	3	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	23-Jul-2019	23-Jul-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 3 female American Bullies dogs (Gaia, 3 years old, 25 kg; Princess, 2 years old and 18 kg; Valentina, 3 years old and 20 kg) received FRONTLINE SPRAY 250 ML (FRONTLINE) (003/18A, exp date is unknown, topical, belly, chest, back and next to head) for the first time, administered by the reporter on 23 Jul 2019 for flea treatment. Lack of efficacy is suspected because the dogs remain with live fleas. According to the reporter, 'he had to purchase FL pipettes to treat the animals', however, it was not informed if these pipettes have been in fact administered to the dogs. Environment not treated. No further information is available.
30-Aug-2019	UAE; 19BR003867; SP; Brazil	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: X Sex qualifier: Unknown Age: - Weight: 2.5 - 5 kg	2	2	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	Jul-2019	Jul-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 Domestic Shorthair cats (crossbred) (Patcho, male, unknown age, 5 kg; Eva, female, 5 months old, 2.5 kg) received one pipette of FRONTLINE SPOT-ON CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades) each, for the first time, administered by the reporter on Jul 2019 for flea treatment. Lack of efficacy is suspected because live fleas are still being found on the cats. Environment not treated. Similar case reported on 19BR003868. No further information is available.
30-Aug-2019	UAE; 19BR003868; SP; Brazil	Species: Canine Breed: Small crossbred (<10 Kg) Sex: M Sex qualifier: Unknown Age: 6.00 Month(s) Weight: 2.5 - 5 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	Jul-2019	Jul-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Opala, a male crossbred dog of 6 months old and 6 kg, received one pipette of FRONTLINE SPOT-ON DOGS S (FL) (lot and exp date are unknown, topical, btw the shoulder blades) for the first time, administered by the reporter on Jul 2019 for flea treatment. Lack of efficacy is suspected because live fleas are still being found on the dog. Opala use to be bathed once a week. Environment not treated. Similar case reported on 19BR003867. No further information is available.
03-Sep-2019	UAE; 19BR003874; SP; Brazil	Species: Feline Breed: Feline various breeds Sex: X Sex qualifier: Unknown Age: 1.00 Year(s) Weight: 3 - 3.5 kg	3	3	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	28-Aug-2019*	28-Aug-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pets owner, 3 crossbred cats (Mole, female of 10 years old and 3 kg; Nina, female of 1.5 years old and 3 kg; Thor, male of 1 year old and 3.5 kg) received FRONTLINE SPRAY (FL) (006/18A, exp date unknown, topical, whole body) for the first time, administered by the reporter last week (28 Aug 2019*) for flea treatment. The pets started presenting fleas 1 month prior to FL. Lack of efficacy is suspected because the pets remain with the same quantity of fleas. She visualized 3 live fleas walking on the pets. The cats are bathed monthly and one of them has access to the rooftop of the house. The environment has not been treated. No further information is available.

N/A signifies the information for this field is either not available or not applicable

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

Report printed on 25-Oct-2019 at 8:39:59PM

*indicates Approximate date or weight

Page 51 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00058

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
31-Aug-2019	UAE; 19BR003876; PR; Brazil	Species: Canine Breed: Small crossbred (<10 Kg) Sex: F Sex qualifier: Unknown Age: 1.20 Year(s) Weight: 2 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	28-Aug-2019	28-Aug-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Maya, a female crossbred dog of 1.2 years old and 2 kg, received one pipette of FRONTLINE PLUS DOGS S (FL) (lot and exp date are unknown, topical, btw the shoulder blades) for the first time, administered by the reporter on 28 Aug 2019 for flea treatment. Lack of efficacy is suspected because fleas were still being seen after product administration, so, on 1 Sep 2019 Nexgard® was administered and the pet is no longer presenting ectoparasites. There are an unknown number of untreated animals (unknown species) living in the same household. Environment not treated. No further information is available.
01-Sep-2019	UAE; 19BR003878; PR; Brazil	Species: Canine Breed: Poodle (Miniature) Sex: M Sex qualifier: Unknown Age: 8.00 Year(s) Weight: 8 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	2016*	01-Sep-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Bob, a male Poodle of 8 years old and 8 kg, received one pipette of FRONTLINE PLUS DOGS S (FL) (005/18, Jan 2020, topical, btw the shoulder blades) administered by the reporter on 1 Sep 2019 for flea treatment. Lack of efficacy is suspected because fleas are still being found on the dog. FL has been administered every 2 months 'since always' (2016*) with no issue. Bob use to be bathed at a pet store every 15 days. According to the reporter, there are stray dogs probably untreated that usually stay on the street, next to the house. Environment not treated. Similar case reported on 19BR003879. No further information is available.
01-Sep-2019	UAE; 19BR003879; PR; Brazil	Species: Canine Breed: Large crossbred (>20 Kg) Sex: F Sex qualifier: Unknown Age: 5.00 Year(s) Weight: 38 - 45 kg	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	2016*	01-Sep-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 female crossbred dogs (Fiona, 9 years old, 45 kg; Lucy, 5 years old, 38 kg) received one pipette of FRONTLINE PLUS DOGS L (FL) (lot and exp date are unknown, topical, btw the shoulder blades) each, administered by the reporter on 1 Sep 2019 for flea treatment. Lack of efficacy is suspected because fleas are still being found on the dogs. FL has been administered every 2 months 'since always' (2016*) with no issue. There is one dog living in the same household that use to be bathed at a pet store every 15 days. According to the reporter, there are stray dogs probably untreated that usually stay on the street, next to the house. Environment not treated. Similar case reported on 19BR003878. No further information is available.
02-Sep-2019	UAE; 19BR003882; SP; Brazil	Species: Feline Breed: Domestic Shorthair (Crossbred) Sex: X Sex qualifier: Unknown Age: 1.90 Year(s) Weight: 3.7 - 6 kg	3	3	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	29-Aug-2019	29-Aug-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 3 crossbred cats (Salomão, male, 9 years old, 5 kg; Bibi, female, 7 years old, approx. 3.7 kg; Pirulito, male, 1.9 years old, 6 kg) received one pipette of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades) each, administered by the reporter on 29 Aug 2019 for flea treatment. Lack of efficacy is suspected because live fleas are still being found on the cats. FL has been administered in the past (every 6 months each cat receives '2 pipettes with a 15-day interval btw the 2 applications') with no issue since date not informed. According to the reporter, the cats eventually have access to the house's garden. Environment not treated. No further information is available.
02-Sep-2019	UAE; 19BR003884; SP; Brazil	Species: Canine Breed: Retriever	1	1	0	Product used: FIPRONIL 10%/S	29-Aug-2019	29-Aug-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Apolo, a male Golden Retriever of unknown age and 48 kg, received one pipette of FRONTLINE PLUS DOGS XL (FL)

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 52 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00059

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		(Golden) Sex: M Sex qualifier: Unknown Age: - Weight: 48 kg				METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes					(008/18B, exp date is unknown, topical, btw the shoulder blades) administered by the reporter on 29 Aug 2019 for flea treatment. Lack of efficacy is suspected because fleas are still being found on the dog. FL has been administered every 6 months since date not informed with no issue. Environment not treated. Similar cases reported on 19BR003885 and 19BR003886. No further information is available.
02-Sep-2019	UAE; 19BR003885; SP; Brazil	Species: Canine Breed: Shih Tzu Sex: F Sex qualifier: Unknown Age: - Weight: 8 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	29-Aug-2019	29-Aug-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Kate, a female Shih Tzu of unknown age and approx. 8 kg, received one pipette of FRONTLINE PLUS DOGS S (FL) (lot and exp date are unknown, topical, btw the shoulder blades) administered by the reporter on 29 Aug 2019 for flea treatment. Lack of efficacy is suspected because fleas are still being found on the dog. FL has been administered every 6 months since date not informed with no issue. Environment not treated. Similar cases reported on 19BR003884 and 19BR003886. No further information is available.
02-Sep-2019	UAE; 19BR003886; SP; Brazil	Species: Canine Breed: Medium crossbred (10 - 20 Kg) Sex: F Sex qualifier: Unknown Age: - Weight: 15 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	29-Aug-2019	29-Aug-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Princesa, a female crossbred dog of unknown age and 15 kg, received one pipette of FRONTLINE PLUS DOGS M (FL) (lot and exp date are unknown, topical, btw the shoulder blades) administered by the reporter on 29 Aug 2019 for flea treatment. Lack of efficacy is suspected because fleas are still being found on the dog. FL has been administered every 6 months since date not informed with no issue. Environment not treated. Similar cases reported on 19BR003884 and 19BR003885. No further information is available.
03-Sep-2019	UAE; 19BR003888; RJ; Brazil	Species: Feline Breed: Feline (various breeds) Sex: X Sex qualifier: Unknown Age: - Weight: Unknown	5	5	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	27-Aug-2019	03-Sep-2019*	10 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, 5 cats of unknown signalment were treated with FRONTLINE PLUS (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter around 24 Aug 2019 (estimated date), for flea treatment. Lack of efficacy is suspected because the animals remain with fleas. They have no access to the street and they have no contact with other animals. This is the extent of the information available. UPDATE 6 SEP 2019 - The owner was contacted and reported that she applied one vial of FRONTLINE PLUS CATS (topical, btw the shoulder blades) to each her 5 mixed breed cats of 2 years old to 16 years old and 4 to 7 kg, on 27 Aug 2019. The number of fleas has decreased, but the owner still sees fleas on her pets. Environment not treated. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided). No further information is expected.
02-Sep-2019	UAE; 19BR003891; -; Brazil	Species: Feline Breed: Feline (various breeds)	2	2	0	Product used: FIPRONIL SPRAY	14-Aug-2019*	14-Aug-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pets owner, Charlotte and Chanel, 2 female crossbred cats of 9 months old and 2.5 kg, received FRONTLINE SPRAY (FL) (lot and exp date

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 53 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00060

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex: F Sex qualifier: Unknown Age: 9.00 Month(s) Weight: 2.5 kg				Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)					unknown, topical, btw the shoulder blades) for the first time, administered by the reporter approximately 20 days ago (14 Aug 2019*) for flea treatment. The owner believes that they already had fleas when they were adopted 9 months ago. Lack of efficacy is suspected because the pets remain with fleas. The cats do not have outdoor access. The environment has not been treated. Related case reported on 19BR003892. No further information is available.
02-Sep-2019	UAE; 19BR003892; -, Brazil	Species: Canine Breed: Canine various breeds Sex: F Sex qualifier: Unknown Age: 7.00 Month(s) Weight: 4 - 5.5 kg	2	2	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	19-Aug-2019*	19-Aug-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pets owner, 2 female dogs (Jully, small crossbred dog of 7 months old and 4 kg; Meg, Shih Tzu of 4.5 years old and 5.5 kg) received FRONTLINE SPRAY (FL) (lot and exp date unknown, topical, btw the shoulder blades) for the first time, administered by the reporter approximately 15 days ago (19 Aug 2019*) for flea treatment. The owner believes that they got fleas when she adopted 2 cats (see case 19BR003891) 9 months ago. Lack of efficacy is suspected because the pets remain with fleas. Meg has flea allergy dermatitis and used to be treated with FRONTLINE PIPETTE and NEXGARD in the past with no issue. The dogs have outdoor access. The environment has not been treated. No further information is available.
04-Sep-2019	UAE; 19BR003903; SP; Brazil	Species: Canine Breed: Pit Bull Sex: F Sex qualifier: Unknown Age: 14.00 Month(s) Weight: 30 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	29-Aug-2019	04-Sep-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Nine, a female Pit Bull of 14 months old and 30 kg, was treated, for the first time, with one vial of FRONTLINE PLUS DOG L (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 29 Aug 2019, for tick treatment. The dog started presenting ticks 1 month prior to FL. Lack of efficacy is suspected because the pet remains with ticks. The animal is bathed every 15 days. The environment was treated once with Butox® on the same date of FL administration. FL was used on other dog in the past with no issue. No further information is expected.
03-Sep-2019	UAE; 19BR003911; SP; Brazil	Species: Canine Breed: Small crossbred (<10 Kg) Sex: F Sex qualifier: Unknown Age: 3.00 Month(s) Weight: 3.6 kg	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	10-Aug-2019	10-Aug-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Luna, a female crossbred of approx. 3 months old and 3.6 kg, received FRONTLINE SPRAY 100 ML (FL) (002/19A, exp date is unknown, topical, whole body) for the first time, administered by the reporter on 10 Aug 2019 and approx. on 25 Aug 2019* for flea treatment. Lack of efficacy is suspected because live fleas are still being found on the pet. Luna use to be bathed once a week. Environment not treated. Similar case reported on 19BR003912. No further information is available.
03-Sep-2019	UAE; 19BR003912; SP; Brazil	Species: Feline Breed: Domestic Shorthair (Crossbreed)	2	2	0	Product used: FIPRONIL SPRAY Other products	10-Aug-2019	10-Aug-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 female crossbred cats (Meg, 6 years old, 3.5 kg; Nina, 13 years old, 2 kg) received FRONTLINE SPRAY 100 ML (FL) (002/19A, exp date is unknown, topical, whole body) each, administered by

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 54 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00061

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex: F Sex qualifier: Unknown Age: 6.00 Year(s) Weight: 2 - 3.5 kg				used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes					the reporter on 10 Aug 2019 and on 25 Aug 2019* for flea treatment. Lack of efficacy is suspected because live fleas are still being found on the pets. FL has been applied in the past (dose frequency and 1st administration date are unknown) with no issue. Environment not treated. Similar case reported on 19BR003911. No further information is available.
03-Sep-2019	UAE; 19BR003913; MG; Brazil	Species: Canine Breed: Small crossbred (<10 Kg) Sex: F Sex qualifier: Unknown Age: 5.00 Year(s) Weight: 9 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	2014	12-Aug-2019	20 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Belinha, a female crossbred dog of 5 years old and 9 kg, received one pipette of FRONTLINE PLUS DOGS S (FL) (022/18A, exp date is unknown, topical, btw the shoulder blades) administered by the reporter on 23 Jul 2019 for flea treatment. Lack of efficacy is suspected because since 12 Aug 2019 live fleas returned to be found on the dog. FL has been administered every 3 months since 2014 with no issue. Environment treated with K-Othrine®. No further information is available.
29-Aug-2019	UAE; 19BR003915; SP; Brazil	Species: Feline Breed: Feline various breeds Sex: F Sex qualifier: Unknown Age: 3.00 Month(s) Weight: 1 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	25-Aug-2019*	29-Aug-2019*	4 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Mia, a female mixed breed cat of 3 months old and 1 kg, was treated, for the first time, with one vial of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical btw the shoulder blades), applied by the reporter around 25 Aug 2019, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. Environment not treated. There is one more cat in this household with the same issue (see case 19BR003852). The owner also complained that her two dogs received FL one week earlier and she believes that they have fleas because they are also scratching themselves (see case 19BR003916). No further information is available.
04-Sep-2019	UAE; 19BR003916; SP; Brazil	Species: Canine Breed: Canine various breeds Sex: M Sex qualifier: Unknown Age: 6.00 Year(s) Weight: Unknown	2	2	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	18-Aug-2019*	04-Sep-2019*	17 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, two male dogs of 6 years old (Bob, Dachshund, unknown weight; Nick, Maltese, unknown weight), were treated with FRONTLINE SPOT-ON DOG S (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter around 18 Aug 2019, for flea control. The owner believes that her dogs have fleas because they are scratching themselves, but no fleas were seen. Environment not treated. FL was applied in the past with no issue (dose frequency is unknown and first administration was not provided). There are two cats in this household that received FL and they have fleas (see cases 19BR003852 and 19BR003915). No further information is expected.
04-Sep-2019	UAE; 19BR003933; PA; Brazil	Species: Canine Breed: Medium crossbred (10 - 20 Kg) Sex: F Sex qualifier: Unknown Age: 7.00 Year(s) Weight: 12 kg	3	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous	15-Aug-2019*	15-Aug-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, a female medium mixed breed dog (other signalment is unknown) was treated with one vial of FRONTLINE PLUS (unsubstantiated) (FL) (lot, exp date, route and location are unknown), applied by the reporter three weeks ago (14 Aug 2019). Lack of efficacy is suspected because the pet remains with ectoparasites (details not provided). This is the extent of the information available. UPDATE 10 SEP 2019 - The owner was contacted and reported that Maria, a female medium crossbred dog of 7 years old and 12 kg, was treated with one vial of

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 55 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00062

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Was the product used ok?: Yes					FRONTLINE PLUS DOG M (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter around 15 Aug 2019, for tick treatment. The dog started presenting ticks 1 week prior FL use. Lack of efficacy is suspected because the pet remains with ticks. Environment treated with an unknown product. the dog dog is bathed weekly and have outdoor access. There are two more dogs in this household that were treated with FL and they have no issue. FL has been applied with no issue every 6 months since date not specified. No further information is expected.
05-Sep-2019	UAE; 19BR003935; RS; Brazil	Species: Canine Breed: Medium crossbred (10 - 20 Kg) Sex: F Sex qualifier: Unknown Age: 6.00 Month(s) Weight: 10 kg	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	10-Aug-2019*	10-Aug-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, one dog of unknown signalment received, for the first time, FRONTLINE SPRAY (FL) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (1 Aug 2019 - chosen at random), for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. In addition, it is scratching itself due to fleas. The owner used to apply vials of FL in the past with no issue (dose frequency is unknown and first application was not provided). This is the extent of the information available. UPDATE 9 Sep 2019 – The pet owner was contacted and reported that Ayla, a female crossbred dog of 6 months old and 10 kg received FRONTLINE SPRAY 100 mL (FL) (005/18, Sep 2020, topical, back) for the first time, applied by the reporter on approx. 10 Aug 2019 for flea treatment. Lack of efficacy was suspected because live fleas were still being found on the dog so on approx. 25 Aug 2019 FL was applied once again and Ayla remains with fleas and she is scratching herself due to the flea presence. Ayla use to be bathed once a week and use to be frequently taken for walking outdoors to a place that is highly frequented by dogs of unknown origin. According to the reporter, after going outdoors the dog always comes back home presenting with fleas. Environment not treated. Similar case reported on 19BR004006. No further information is available.
05-Sep-2019	UAE; 19BR003940; PE; Brazil	Species: Canine Breed: Poodle (Miniature) Sex: M Sex qualifier: Unknown Age: 15.00 Year(s) Weight: 12 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	01-Jan-2015*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Ralf Raphael, a male crossbred dog (Poodle x Cocker) of 15 years old and 12 kg, was treated with FRONTLINE PLUS (FL) (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (1 Jan 2015*), for unknown reason. The owner believes that FL was not working. FL was used in the past with no issue (dose frequency is unknown and date of first administration was not provided). The owner also complained about the lack of efficacy of NEXGARD (see cases 19BR003875 and 19BR003939). This is the extent of the information available.
06-Sep-2019	UAE; 19BR003943; -; Brazil	Species: Feline Breed: Feline (unknown) Sex: F Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the	29-Aug-2019	05-Sep-2019	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, one female cat of unknown signalment received 1 dose of FRONTLINE PLUS CATS (FL) (lot, exp date, topical, btw the shoulder blades), administered by the reporter on 29 Aug 2019 for flea treatment. Lack of efficacy is suspected because one week after treatment the reporter visualized a lot of fleas on the pet during the bath. The cat remains with fleas and most of them are big. This is the extent of the information available.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 56 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00063

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						product used ok?: Yes					
06-Sep-2019	UAE; 19BR003946; MG; Brazil	Species: Canine Breed: Boxer Sex: F Sex qualifier: Unknown Age: - Weight: 25 kg	2	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	24-Aug-2019*	24-Aug-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Duquesa, a female Boxer of around 25 kg and unknown age, was treated with one vial of FRONTLINE PLUS DOG L (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter around 24 Aug 2019, for flea treatment. The owner believes that his dog has fleas because she is scratching herself, but no fleas were seen. Environment not treated. The dog goes out for walks regularly at a park nearby and is bathed every 15 days. There is a dog that previously had fleas and was treated with FL one week earlier living in this house, and has no more fleas. The reporter believes that Duquesa got fleas from this dog. No further information is expected.
06-Sep-2019	UAE; 19BR003960; MG; Brazil	Species: Canine Breed: Blue Heeler Sex: F Sex qualifier: Unknown Age: 40.00 Day(s) Weight: 2.5 kg	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	21-Aug-2019	21-Aug-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Aisha, a female Blue Heeler of 40 days old and 2.5 kg, received FRONTLINE SPRAY 250 ML (FL) (004/18A, exp date is unknown, topical, btw the shoulder blades, back, chest and belly) for the first time, administered by the reporter on 21 Aug 2019, 25 Aug 2019 and 4 Sep 2019 for flea/tick treatment. Lack of efficacy is suspected because live fleas and ticks are still being found on the pet. There are 2 other dogs living in the same household and they have not been simultaneously treated, and 2 dogs that were treated with FL and also remain with fleas and ticks (see case 19BR003961). Environment has not been treated either. No further information is available.
06-Sep-2019	UAE; 19BR003961; MG; Brazil	Species: Canine Breed: Canine various breeds Sex: F Sex qualifier: Unknown Age: 5.00 Year(s) Weight: 44 - 49 kg	2	2	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	01-Sep-2019	01-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 female dogs of 5 years old (Frontline, German Shepherd Dog, approx. 44 kg; Pandora, Rottweiler, approx. 49 kg) received FRONTLINE SPRAY 250 ML (FL) (004/18A, exp date is unknown, topical, btw the shoulder blades, back, chest and belly) for the first time, administered by the reporter on 1 Sep 2019 for flea/tick treatment. The reporter says that the ectoparasites came from a dog that was recently brought to this house (see case 19BR003960). Lack of efficacy is suspected because live fleas and ticks are still being found on the pets. There are 2 other dogs living in the same household and they have not been simultaneously treated. Environment has not been treated either. No further information is available.
06-Sep-2019	UAE; 19BR003964; MG; Brazil	Species: Canine Breed: Yorkshire Terrier Sex: F Sex qualifier: Unknown Age: 3.00 Year(s) Weight: 2.2 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous	06-Sep-2019	06-Sep-2019	0 Day(s)	D-D	Suspected Adverse Event: As reported by the pet owner, Luna, a female Yorkshire Terrier of 3 years old and 2.2 kg, received FRONTLINE DOGS S (unsubstantiated) (FL) (lot and exp date are unknown, topical, btw the shoulder blades) administered by the reporter on 6 Sep 2019 at 6:30 PM for unknown reason. The dog was in good health prior to product administration. Two hours post FL administration, Luna experienced vomiting and agitation. A few time later she experienced apathy and trembling. Luna was taken to the vet clinic and, according to the reporter, the DVM suspects that the animal had an intoxication caused by FL. It is unknown if

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 57 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00064

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Was the product used ok?: Yes					any treatment has been provided and Luna's current health status was not informed. This is the extent of the information available. UPDATE 16 AUG 2019 – The pet owner was contacted and reported that Luna is 'improving'. No further information is available.
09-Sep-2019	UAE; 19BR003965; SP; Brazil	Species: Canine Breed: Lhasa Apso Sex: F Sex qualifier: Unknown Age: 26.00 Month(s) Weight: 7 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	02-Jul-2019*	25-Jul-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Meg, a female Lhasa Apso of 26 months old and 7 kg, was treated with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on date not specified (2 Jul 2019*) for flea and tick prevention. Lack of efficacy is suspected because the pet got fleas approximately 3 weeks after treatment (25 Jul 2019*). Another administration of FL was made on 2 Aug 2019 and the dog remains with a few fleas. The dog has outdoor access 2 times per month and is bathed every 15 days. Environment not treated. FL used to be applied every 3 months since date not specified (2017*) and has been applied monthly lately (since date not provided). No further information is expected.
09-Sep-2019	UAE; 19BR003968; MG; Brazil	Species: Canine Breed: Canine various breeds Sex: F Sex qualifier: Unknown Age: 2.00 Month(s) Weight: 0.8 - 2.3 kg	2	2	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	23-Aug-2019	23-Aug-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, two dogs (Marry, a female Poodle of 9 years old and 2.3 kg; Pitty, a female small crossbred dog of 2 months and 800 g) were treated, for the first time, with FRONTLINE SPRAY (FL) (003/18b, unknown exp date, topical, whole body), applied by the reporter on 23 Aug 2019, for flea/tick treatment. Lack of efficacy is suspected because the number of fleas has increased. Environment treated with deltamethrin. The dogs have no outdoor access. FL pipette was applied in the past and the product was not effective as well (See case 19BR003969). No further information is expected.
09-Sep-2019	UAE; 19BR003969; MG; Brazil	Species: Canine Breed: Poodle (Miniature) Sex: F Sex qualifier: Unknown Age: 9.00 Year(s) Weight: 2.3 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	N/A	01-Jul-2017*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Marry, a female Poodle of 9 years old and 2.3 kg, was treated with one vial of FRONTLINE (FL) (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (Jul 2018* - chosen at random). The owner believes that FL was not effective (details not provided). Similar case reported on 19BR003968. No further information is expected.
10-Sep-2019	UAE; 19BR003973; RJ; Brazil	Species: Feline Breed: Feline various breeds Sex: X Sex qualifier: Unknown Age: 2.50 Year(s) Weight: 4 kg	2	2	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	03-Sep-2019	03-Sep-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 crossbred cats (Bebe, male of approximately 2.5 years old and 4 kg; Perola, female of approximately 3.5 years old and 4 kg) received FRONTLINE SPRAY (FL) (002/18, exp date Jun 2020, topical, whole body) for the first time, administered by the reporter on 3 Sep 2019 (Bebe) and on 4 Sep 2019 (Perola) for flea treatment. The pets started presenting fleas 1 month prior to FL. Lack of efficacy is suspected because the pets remain with fleas. She visualized fleas walking on the pets, on the floor and on herself. FRONTLINE PIPETTE (unsubstantiated) was used in the past with no issue. The cats are not bathed very often and do not have access to the street. There is a dog treated with FL living in this house and it is unknown if it has fleas. The environment has

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 58 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00065

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											not been treated. No further information is available.
09-Sep-2019	UAE; 19BR003976; SP; Brazil	Species: Canine Breed: Yorkshire Terrier Sex: M Sex qualifier: Unknown Age: 4.00 Year(s) Weight: 6 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	28-Aug-2019	08-Sep-2019*	11 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Ozzy, a male Yorkshire Terrier of 4 years old and 6 kg, received one pipette of FRONTLINE PLUS DOGS S (022/18B, exp date is unknown, topical, btw the shoulder blades) administered orally by the reporter on 28 Aug 2019 for flea treatment. Lack of efficacy is suspected because on approx. 8 Sep 2019 three live fleas were found on the dog's belly. He also continues to scratch intensely ('he is pulling out his fur') and has skin desquamation. The fleas were manually removed and the reporter attributed the mentioned symptoms to the flea presence. Ozzy was taken to the vet clinic and, according to the reporter, 'the DVM confirmed that FL was not effective'. An injection was administered to the dog and Atrovent® and an unknown ectoparasiticide product were also prescribed. The ectoparasiticide product was administered on 9 Sep 2019 and Ozzy is no longer with fleas. The owner added that Ozzy use to be bathed once a week, he has 'sensitivity' to grooming blades and use to be taken for walking outdoors twice a day. FL has been applied in the past since date not informed but there was confusing information regarding dose frequency. Also according to her, the flea infestation was seen during 1 year prior to FL administration and, since then, 'multiple attempts to control the issue have been performed unsuccessfully' (no details were provided). Environment use to be 'regularly treated' with K-Othrine®. No further information is available.
11-Sep-2019	UAE; 19BR003991; SP; Brazil	Species: Canine Breed: Beagle Sex: M Sex qualifier: Unknown Age: 5.00 Year(s) Weight: 13 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: Unknown tablet for flea treatment; Route: Topical / Cutaneous Was the product used ok?: Yes	09-Sep-2019	11-Sep-2019	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Spike, a male Beagle of 5 years old and 13 kg, was treated, for the first time, with one vial of FRONTLINE SPOT-ON DOG M (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 9 Sep 2019, for flea treatment. An unknown tablet for flea treatment was also administered prior to FL (date not specified - 8 Sep 2019*). Lack of efficacy is suspected because new fleas have been found on the pet. Environment treated with deltamethrin. Sometimes the pet has outdoor access. No further information is available.
11-Sep-2019	UAE; 19BR003994; SP; Brazil	Species: Canine Breed: Shih Tzu Sex: F Sex qualifier: Unknown Age: 9.00 Month(s) Weight: 5.2 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	30-Aug-2019	10-Sep-2019	11 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Princesa, a female Shih Tzu of 9 months old and 5.2 kg, was treated, for the first time, with one vial of FRONTLINE SPOT-ON DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 30 Aug 2019, for flea/tick control. Lack of efficacy is suspected because fleas and ticks have been found on her pet since 10 Sep 2019. Environment not treated. The pet has outdoor access and is bathed every 7 to 8 days. Revolution® was used in the past with no issue. No further information is expected.
09-Sep-2019	UAE; 19BR003995; SP; Brazil	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: X Sex qualifier:	5	5	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products	05-Sep-2019	05-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 5 neutered mixed crossbred cats of 4 to 9 years old and 2.2 to 8 kg, received one pipette of FRONTLINE PLUS CATS (FL) (007/18A, exp date is unknown, topical, btw the shoulder blades) each, for the first time, administered by the reporter on 5 Sep 2019 for flea treatment. The cats started presenting fleas 5 days prior to FL.

N/A signifies the information for this field is either not available or not applicable

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

Report printed on 25-Oct-2019 at 8:39:59PM

*indicates Approximate date or weight

Page 59 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00066

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Unknown Age: 4.00 Year(s) Weight: 2.2 - 8 kg				used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes					Lack of efficacy is suspected because live fleas are still being found on the cats. According to the reporter, the animals do not have outdoor access and during the summer they use to be bathed once a month. There is 1 cat living in the same household that has not been treated. There is also 1 dog and he has been simultaneously treated with Revolution®. Environment use to be treated once a week with Fleegard® and Butox®. No further information is available.
11-Sep-2019	UAE; 19BR003998; -; Brazil	Species: Canine Breed: Shih Tzu Sex: F Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	09-Sep-2019	09-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, one female Shih Tzu of unknown signalment was treated with FRONTLINE SPRAY (FL) (lot, exp date, route and location are unknown), applied by the reporter on 9 Sep 2019, for flea treatment. The dog has outdoor access and got fleas after contact with other animals during a walk. Lack of efficacy is suspected because the pet remains with fleas. Environment not treated. This is the extent of the information available.
09-Sep-2019	UAE; 19BR004006; RS; Brazil	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: M Sex qualifier: Unknown Age: 3.00 Year(s) Weight: 9 kg	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	10-Aug-2019*	10-Aug-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Simba, a male crossbred cat of 3 years old and approx. 9 kg, received FRONTLINE SPRAY 100 mL (FL) (005/18, Sep 2020, topical, back and behind the ears) for the first time, applied by the reporter on approx. 10 Aug 2019* for flea treatment. Lack of efficacy is suspected because the pet remains with live fleas. There is 1 dog that was also treated with FL and has fleas (see case 19BR003935) living in the same household and he is frequently taken for walking outdoors to places that are highly frequented by other dogs of unknown origin. According to the reporter, after going outdoors the dog always comes back home presenting with fleas. Environment not treated. No further information is available. UPDATE 4 Oct 2019 - The pet owner contacted BIAH to report the persistence of fleas and itching in a dog, so, a new case was created by mistake (19BR004561). It was found that there was actually no LOE suspicion for an additional patient and the mentioned dog was actually the same patient of the case 19BR003935. Due to the lack of LOE suspicion the case 4561 was changed to inquiry. No further information is available.
11-Sep-2019	UAE; 19BR004007; RJ; Brazil	Species: Canine Breed: Dachshund Sex: F Sex qualifier: Unknown Age: - Weight: 10 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Species not indicated / recommended)	16-Aug-2019	17-Aug-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Sheron, a female Dachshund of 10 kg and unknown age, received one vial of FRONTLINE PLUS CATS (lot and exp date are unknown, btw the shoulder blades, off-label: species not recommended), applied by the reporter on 16 Aug 2019, for flea control. Lack of efficacy is suspected because the pet got fleas one day after treatment. Outdoor flea control has been performed with Butox®, however, indoor flea control has not been made. FL has been applied every 3 months or so with no issue (date of first application was not provided). No further information is expected.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 60 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00067

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
09-Sep-2019	UAE; 19BR004014; RJ; Brazil	Species: Canine Breed: Rottweiler Sex: M Sex qualifier: Unknown Age: 2.00 Month(s) Weight: 2.2 kg	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	05-Sep-2019	05-Sep-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Logan, a male Rottweiler of 2 months old and 2.2 kg, received FRONTLINE SPRAY 250 mL (FL) (004/18A, Sep 2020, topical, neck, next to tail, belly, face and armpits – off-label use) for the first time, applied by the reporter on 5 and 6 Sep 2019 for flea treatment. Lack of efficacy is suspected because the pet remains with live fleas. According to the reporter, the product was odorless (see PRID 493476 reported on GoTrack). Her hands also became slightly sticky after intentionally spraying the product on them ('her hands did not get 'rough' like the other times she administered FL') – cases of human exposure were reported on 19BR004015 and 19BR004018. There are 2 dogs living in the same household and they have not been simultaneously treated. Environment has not been treated either. No further information is available. 24-OCT-19 QA results received: Investigation completed for FIPRONIL SPRAY Lot# 00418A, expiry 2020-09-30. Case investigated by France - Toulouse. Final complaint evaluation BIAH QA received a product quality complaint for FRONTLINE SPRAY, batch 004/18, on 12 September 2019. The complaint description is odorless. After verification, the batch 004/18 has been produced by the bulk S024. This is the first complaint regarding this defect for this batch. The retention sample is conform (aspect) but we do not open the sample to smell because this complaint will be classified major without impact for market action. The sample complaint is not received. Pictures are attached for this case. Batch record investigation: Manufacturing date: 08/10/2018 - Expiry date: 09/2020 - Manufacturing quantity: 8498 liters. No deviation is associated to this batch and one observation is not associated to this defect. This batch was not concerned by any change control. The results of QC testing are conform at specifications. All parameters verified during manufacturing of this batch of bulk are conform. Root
12-Sep-2019	UAE; 19BR004016; SP; Brazil	Species: Canine Breed: Yorkshire Terrier Sex: M Sex qualifier: Unknown Age: 28.00 Month(s) Weight: 2.4 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	29-Aug-2019	29-Aug-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Jheik, a male Yorkshire of 28 months old and 2.4 kg, was treated, for the first time, with one vial of FRONTLINE SPOT-ON DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 29 Aug 2019, for flea treatment. The dog is bathed monthly at a pet shop and started presenting fleas 1 month prior to FL. Lack of efficacy is suspected because the pet remains with fleas. A tick was visualized after treatment but disappeared later, so lack of efficacy is not suspected in relation to ticks. Environment not treated. No further information is expected.
12-Sep-2019	UAE; 19BR004027; SP; Brazil	Species: Canine Breed: Pug Sex: F Sex qualifier: Unknown Age: 1.00 Year(s) Weight: 6.5 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	17-Aug-2019	12-Sep-2019*	26 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Pandora, a female Pug of 1 year old and 6.5 kg, was treated, for the first time, with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 17 Aug 2019, for flea control. Lack of efficacy is suspected because fleas have been found on her pet. The dog is bathed every 15 days. Environment not treated. No further information is expected.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 61 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00068

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
13-Sep-2019	UAE; 19BR004032; RJ; Brazil	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	10	10	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	N/A	2013*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, around 10 dogs of unknown signalment received FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, back - low dose), applied by the reporter approximately 6 years ago (2013*), for flea treatment. Fleas have died, however new fleas were seen on his dogs. Environment treated with Triatox® and Talfon®. His issue was solved a long time ago with an unknown product. The owner also complained that one of his dogs presented a reaction after application of one vial of FL PIPETTE (see case 19BR004033). No further information is available.
13-Sep-2019	UAE; 19BR004033; RJ; Brazil	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	N/A	2013*	0 Day(s)	D-D	Suspected Adverse Event: As reported by the pet owner, one dog of unknown signalment was treated with one vial of FRONTLINE (unsubstantiated) (FL) (lot, exp date, route and location are unknown), applied by the reporter around 2013*. After product application (time to onset is unknown), the pet presented application site burn. Details were not provided. The owner also complained about the lack of efficacy of FL SPRAY (see case 19BR004032). No further information is expected.
13-Sep-2019	UAE; 19BR004036; SC; Brazil	Species: Canine Breed: Border Collie Sex: M Sex qualifier: Unknown Age: 1.00 Year(s) Weight: 25 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	03-Sep-2019	11-Sep-2019	8 Day(s)	D-D	Suspected Adverse Event: As reported by the pet owner, Egeu, a male Border Collie of 1 year old and 25 kg, was treated, for the first time, one vial of FRONTLINE PLUS DOG L (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 3 Sep 2019, for flea control. The pet was in good health prior to NG and has no history of adverse reactions. On 11 Sep 2019, the pet presented application site lesion. No vet care was provided. No further information is available.
13-Sep-2019	UAE; 19BR004056; BA; Brazil	Species: Canine Breed: Medium crossbred (10 - 20 Kg) Sex: F Sex qualifier: Unknown Age: 1.00 Year(s) Weight: 18 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	Apr-2019*	13-Sep-2019	13 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Mel, a female crossbred dog of 1 year old and 18 kg, received one pipette of FRONTLINE PLUS DOGS M (FL) (lot and exp date are unknown, topical, back) administered by the reporter on 31 Aug 2019 for ectoparasite control. Lack of efficacy is suspected because live fleas are being found on the dog since 13 Sep 2019. On 13 Sep 2019 approx. 5 fleas were manually removed by the pet owner as soon as they were visualized. FL has been administered every 2 months since date not informed (Apr 2019*) with no issue. Mel is eventually taken for walking outdoors. Environment not treated. No further information is available.

N/A signifies the information for this field is either not available or not applicable

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

Report printed on 25-Oct-2019 at 8:39:59PM

*indicates Approximate date or weight

Page 62 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00069

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
14-Sep-2019	UAE; 19BR004062; -, Brazil	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	01-Sep-2019*	14-Sep-2019*	13 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, 2 dogs of unknown signalment received FRONTLINE SPRAY (FL) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (1 Sep 2019 - chosen at random), for flea/tick control. Lack of efficacy is suspected because fleas have been found on her dogs. FL was applied in the past with no issue (dose frequency is unknown and first administration was not provided). The reporter says that FL is highly effective for ticks but no longer effective for fleas. There are also 4 cats treated with FL with the same issue living in this house (see case 19BR004063). No further information is expected.
14-Sep-2019	UAE; 19BR004063; -, Brazil	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	4	4	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	01-Sep-2019*	14-Sep-2019*	13 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, 4 cats of unknown signalment received FRONTLINE SPRAY (FL) (lot and exp date unknown, topical, location unknown), applied by the reporter on date not specified (1 Sep 2019 - chosen at random), for flea/tick control. Lack of efficacy is suspected because fleas have been found on her cats. FL was applied in the past with no issue (dose frequency is unknown and first administration was not provided). The reporter says that FL is highly effective for ticks but no longer effective for fleas. There are also 2 dogs treated with FL with the same issue living in this house (see case 19BR004062). No further information is expected.
16-Sep-2019	UAE; 19BR004068; RJ; Brazil	Species: Canine Breed: Medium crossbred (10 - 20 Kg) Sex: F Sex qualifier: Unknown Age: 5.00 Year(s) Weight: 11 kg*	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	08-Sep-2019*	08-Sep-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Nina, a female medium crossbred dog of more than 10 kg and 5 years old, was treated, for the first time, with FRONTLINE SPRAY (FL) (002/18B, unknown exp date, topical, whole body), applied by the reporter around 8 Sep 2019, for flea treatment. The product was administered after bath and the animal's hair and skin were still wet. The dog is bathed every 15 days or so. Lack of efficacy is suspected because the pet remains with fleas. In addition, ticks also started appearing on her pet. Environment treated with FL. No further information is expected.
16-Sep-2019	UAE; 19BR004074; ES; Brazil	Species: Canine Breed: Chihuahua Sex: M Sex qualifier: Unknown Age: 8.00 Year(s) Weight: 6 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	06-Sep-2019	15-Sep-2019*	9 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Pingo, a male Chihuahua of 8 years old and 6 kg, was treated with one vial of FRONTLINE PLUS DOG S (014/18A, unknown exp date, topical, btw the shoulder blades), applied by the reporter on 6 Sep 2019, for tick treatment. After product application, ticks have died, however, the owner believes that FL is not working because fleas have been found on her pet. Environment not treated. The pet has outdoor access. FL has been applied with no issue every 40 days since 2009*. No further information is expected.
14-Sep-2019	UAE; 19BR004081; RJ; Brazil	Species: Canine Breed: Yorkshire	1	1	0	Product used: FIPRONIL 10%/S	10-Aug-2019	20-Aug-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Sandy, a female Yorkshire of 17 months old and 2.6 kg, was treated with one vial of FRONTLINE PLUS DOG S (014/18A,

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 63 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00070

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Terrier Sex: F Sex qualifier: Unknown Age: 17.00 Month(s) Weight: 2.6 kg				METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes					unknown exp date, topical, btw the shoulder blades), applied by the reporter on 10 Aug 2019 and 10 Sep 2019, for flea/tick control. Lack of efficacy is suspected because attached ticks have been found on her pet. The owner removes the ectoparasites, but new ticks are still appearing. The pet has outdoor access. Environment not treated. No further information is expected.
16-Sep-2019	UAE; 19BR004082; -; Brazil	Species: Canine Breed: Chowchow Sex: F Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	2019*	2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, an intact female Chowchow of unknown signalment received FRONTLINE SPRAY (FL) (lot, exp date, route and location are unknown) applied by the reporter on date not informed (2019*) for tick treatment. According to the reporter, the product was not effective. The reporter suspects that the product was not effective because she may have misapplied it. This is the extent of the information available for now.
14-Sep-2019	UAE; 19BR004083; RJ; Brazil	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	13-May-2019*	13-May-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, one dog of unknown signalment was treated with FRONTLINE PLUS (unsubstantiated) (FL) (lot, exp date, route and location are unknown), applied by the reporter around one month ago (13 Aug 2019 - estimated date), for tick treatment. The owner believes that FL was not working because she found some ticks on her dog. Environment treated weekly with Butox®. The pet has no outdoor access. FL was applied monthly for the past months (since May 2019*) and, according to the owner, the product was not effective since then. So, Bravecto® was administered on date not specified (13 Sep 2019*) and the pet is currently free of ticks. However, she has 3 more dogs that were treated with FL and they still have ticks (See cases 19BR004084 and 19BR004085). The reporter used FL in the past with no issue (details were not provided). No further information is expected.
14-Sep-2019	UAE; 19BR004084; RJ; Brazil	Species: Canine Breed: Pinscher (Miniature) Sex: F Sex qualifier: Unknown Age: 20.00 Month(s) Weight: 3 - 3.2 kg	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	13-May-2019*	13-May-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 female Pinschers (Pretinha, 10 years old and around 3.2 kg; Belinha, 20 months old and 3 kg) were treated with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades) each, applied by the reporter on 13 Sep 2019, for tick treatment. Lack of efficacy is suspected because the animals remain with ticks, although on 16 Sep 2019 the quantity of ticks has decreased. Environment treated weekly with Butox®. The animals have no outdoor access. FL has been applied monthly for the past 4 months (since May 2019*) and, according to the owner, the product was not effective since then. There are 2 other dogs that also continued presenting ticks after FL living in this house (see cases 19BR004083 and 19BR004085). The reporter used FL in the past with no issue (details were not provided). No further information is expected.
14-Sep-2019	UAE; 19BR004085; RJ; Brazil	Species: Canine Breed: Small crossbred (<10 Kg)	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE	13-Sep-2019	13-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Aurora, a female small crossbred dog of 6 months old and 2.4 kg, was treated, for the first time, with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 64 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00071

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex: F Sex qualifier: Unknown Age: 6.00 Month(s) Weight: 2.4 kg				9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes					shoulder blades), applied by the reporter on 13 Sep 2019, for flea treatment. Lack of efficacy is suspected because the pet remains with ticks, although the quantity of ticks has decreased. Environment treated weekly with Butox®. The animal has no outdoor access. There are 3 other dogs that also continued presenting ticks after FL living in this house (see cases 19BR004083 and 19BR004084). No further information is expected.
16-Sep-2019	UAE; 19BR004092; -; Brazil	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	Sep-2019*	Sep-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via distributor, a dog of unknown signalment received FRONTLINE SPRAY (FL) (unsubstantiated; lot, exp date, route and location are unknown) applied by the reporter on date not informed (Sep 2019* - estimated) for flea/tick treatment. Lack of efficacy is suspected because live ticks and fleas continued to be seen 2 days after product administration and, according to the pet owner, the ectoparasites actually increased in quantity post FL use. The retailer gave 2 tablets of Nexgard® to the pet owner, however, it was not informed if the product was in fact administered and whether the ectoparasite infestation is ongoing. She also informed that the product has a strong odor, so a case was reported on GoTrack (see PRID 496256). Environmental factors are not known. This is the extent of the information available for now. 24-OCT-19 QA results received: Investigation completed for FIPRONIL SPRAY Lot# UNKNOWN, expiry. Case investigated by France - Toulouse. Final complaint evaluation A product quality complaint for FRONTLINE spray 250ML batch unknown, was received by BIAH QA on 18/09/19: The defect reported is a strong odor. 4 complaints were received for odor defects over the past 12 months, (regarding all batches/formats of frontline spray). 2 were for weak odor and 2 for strong odor. Root cause: no root cause established. The product contains a high quantity of isopropyl alcohol, which results in a characteristic normal odor. It could also be due to an alcoholic saturation of the bottle's head space. The product is very stable in normal storage conditions. Once applied on the animal it can react with the hair of the animal depending on the state of the hair. This is sometimes difficult to link the defect with a real product's problem. If the abnormal odor is confirmed after examination of the sample returned, a specific analysis can be performed. If no product is returned, and without the batch number,
17-Sep-2019	UAE; 19BR004093; RJ; Brazil	Species: Canine Breed: Yorkshire Terrier Sex: M Sex qualifier: Unknown Age: 2.50 Year(s) Weight: 5.5 - 6.5 kg*	3	3	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	11-Sep-2019	17-Sep-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, three male Yorkies of 2.5 years old and around 5.5 to 6.5 kg, were treated, for the first time, with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied to each one by the reporter on 11 Sep 2019, for flea control. Lack of efficacy is suspected because fleas have been found on her animals after one of them was taken to a house with treated cats. One of the dogs is allergic and is itching due to the fleas. The fleas that were visualized were removed and it is unknown if the dogs remain with fleas. Environment not treated. No further information is expected.
17-Sep-2019	UAE; 19BR004100;	Species: Canine Breed: Yorkshire	1	1	0	Product used: FIPRONIL	10-Sep-2019	10-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, one dog of unknown signalment received

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 65 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00072

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	SP; Brazil	Terrier Sex: F Sex qualifier: Unknown Age: 7.00 Year(s) Weight: 7 kg				10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes					FRONTLINE (FL) (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (1 Sep 2019* - chosen at random), for flea treatment. The owner believes that FL is not working because the product has not killed the fleas. This is the extent of the information available. UPDATE 18 SEP 2019 - Julie, a female Yorkshire of 7 years old and 7 kg, was treated with one vial of FRONTLINE PLUS DOG S (lot and exp date unknown, topical, btw the shoulder blades), applied by the reporter on 10 Sep 2019, for flea treatment. The dog started presenting fleas 1 week prior to FL. The pet remains with fleas. Environment not treated. The pet has flea allergy dermatitis and is bathed weekly. FL has been applied three times a year with no issue since date not specified. There is a cat treated with unknown product with no fleas living in this house. No further information is expected.
17-Sep-2019	UAE; 19BR004107; AL; Brazil	Species: Canine Breed: Siberian Husky Sex: M Sex qualifier: Unknown Age: 2.00 Month(s) Weight: 5 kg	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	29-Aug-2019	29-Aug-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Zeus, a male Siberian Husky of 2 months old and 5 kg, was treated, for the first time, with FRONTLINE SPRAY (FL) (002/19A, unknown exp date, topical, parts of the body - low dose), applied by the reporter on 29 Aug 2019, for flea/tick treatment. Lack of efficacy is suspected because the pet remains with live ticks and fleas. The dog is bathed every 15 days. Environment treated with an unknown product. No further information is expected.
16-Sep-2019	UAE; 19BR004108; RJ; Brazil	Species: Canine Breed: Spaniel (Cocker) Sex: F Sex qualifier: Unknown Age: 6.00 Year(s) Weight: 10.6 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	25-Jun-2019*	10-Jul-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Sofia, a female Cocker of 6 years old and 10.6 kg, was treated with one vial of FRONTLINE PLUS DOG (FL) (unsubstantiated) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter around 25 Jun 2019 (estimated date), for flea treatment. 15 days post product application, the owner noticed that her dog still had fleas and itching (due to fleas). 45 days later (10 Aug 2019 - estimated date), she applied another vial of FL and she still sees fleas on her pet. Environment treated with cypermethrin. The pet has no outdoor access and has no contact with other animals. FL was applied for the first time around 2 years ago (2017*). No further information is expected.
17-Sep-2019	UAE; 19BR004112; MG; Brazil	Species: Canine Breed: Yorkshire Terrier Sex: M Sex qualifier: Unknown Age: 3.00 Month(s) Weight: 1.8 kg	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment /	26-Jul-2019	26-Jul-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, João, a male Yorkshire Terrier of 3 months old and 1.8 kg, received FRONTLINE SPRAY 100 mL (FL) (002/19A, exp date is unknown, topical, whole body except for the head – off-label use) for the first time, applied by the reporter on 26 Jul, 5 and 16 Aug 2019 for tick treatment. Lack of efficacy is suspected because the pet remains with live ticks. The animal is bathed every 15 days. Environment treated with unknown product. No further information is available.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 66 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00073

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						vaccination program not respected)					
17-Sep-2019	UAE; 19BR004119; RJ; Brazil	Species: Feline Breed: Feline various breeds Sex: X Sex qualifier: Unknown Age: 2.00 Year(s) Weight: 3.500 - 6.000 kg	5	5	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	20-Aug-2019	20-Aug-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 5 cats (Lino, male, 13 years old, 5 kg; Nikita, female, crossbred, 8 years old, 6 kg; Espeto, male, crossbred, 2 years old, 3.5 kg; Baguera, male, Persian, 2.5 years old, 4.5 kg; Ponpydu, male, Ragdoll, 2 years old and 3.5 kg) received one pipette of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, back) each, administered by the reporter on 20 Aug 2019 for flea treatment. Lack of efficacy is suspected because live fleas are still being found on the cats. FL has been administered approx. every 1 or 2 months* since date not informed with no issue. The cats have outdoor access and are bathed every 15 days. Environment has been treated with Butox® and Decaplus®. Vacuum cleaner is also used in the house. No further information is available.
18-Sep-2019	UAE; 19BR004120; SP; Brazil	Species: Canine Breed: Yorkshire Terrier Sex: F Sex qualifier: Unknown Age: 2.00 Year(s) Weight: 1.5 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	29-Aug-2019	18-Sep-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Pietra, a female Yorkshire of 2 years old and 1.5 kg, was treated with one vial of FRONTLINE PLUS (unsubstantiated) (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 29 Aug 2019, for flea control. Lack of efficacy is suspected because fleas have been found on her pet after treatment. Environment treated with Butox®. The dog is bathed weekly. FL has been applied every 3 months with no issue since date not specified. No further information is expected.
18-Sep-2019	UAE; 19BR004122; RJ; Brazil	Species: Canine Breed: Small crossbred (<10 Kg) Sex: F Sex qualifier: Unknown Age: 12.00 Year(s) Weight: 5 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	11-Jul-2019*	11-Jul-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Teca, a female small crossbred dog of 12 years old and 5 kg, was treated with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter last week (11 Sep 2019*), for flea treatment. Flea infestation for the past 3 months (since Jul 2019*). Lack of efficacy is suspected because the pet remains with fleas. Environment treated with deltamethrin. FL has been applied monthly since date not specified. The pet has no outdoor access. There is a cat treated with FRONTLINE PLUS CATS with the same issue living in this house (see case 19BR004123). The owner also complained that FL SPRAY was not effective (see cases 19BR004124 and 19BR004125). No further information is expected.
18-Sep-2019	UAE; 19BR004123; RJ; Brazil	Species: Canine Breed: Small crossbred (<10 Kg) Sex: F Sex qualifier: Unknown Age: 12.00 Year(s) Weight: 5 kg	1	1	0	Product used: FIPRONIL Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	Jan-2018*	Jan-2018*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Teca, a female small crossbred dog of 12 years old and 5 kg, was treated with FRONTLINE SPRAY (FL) (unsubstantiated) (lot and exp date are unknown, topical, whole body), applied by the reporter on date not specified (Jan 2018* - chosen at random), for flea treatment. The product was not effective. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided). There is a cat that was also treated with FL with the same issue living in this house (see case 19BR004125). The owner also complained that FL PLUS DOG S and FL PLUS CATS were not effective (see cases 19BR004122 and 19BR004124). No

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 67 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00074

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											further information is expected.
18-Sep-2019	UAE; 19BR004124; RJ; Brazil	Species: Feline Breed: Feline various breeds Sex: M Sex qualifier: Unknown Age: 6.00 Month(s) Weight: 3.5 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	11-Jul-2019*	11-Jul-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Leopoldo, a male mixed breed cat of 6 months old and 3.5 kg, was treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter last week (11 Sep 2019*), for flea treatment. Flea infestation for the past 3 months (Jul 2019*). Lack of efficacy is suspected because the pet remains with fleas. Environment treated with deltamethrin. FL has been applied monthly with no issue since date not specified. The pet has no outdoor access. There is a dog treated with FRONTLINE PLUS DOGS with the same issue living in this house (see case 19BR004122). The owner also complained that FL SPRAY was not effective (See cases 19BR004123 and 19BR004125). No further information is expected.
18-Sep-2019	UAE; 19BR004125; RJ; Brazil	Species: Feline Breed: Feline various breeds Sex: M Sex qualifier: Unknown Age: 6.00 Month(s) Weight: 3.5 kg	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	Jan-2018*	Jan-2018*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Leopoldo, a male mixed breed cat of 6 months old and 3.5 kg, was treated with FRONTLINE SPRAY (FL) (lot and exp date are unknown, topical, whole body), applied by the reporter on date not specified (Jan 2018*), for flea treatment. The product was not effective. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided). There is a dog that was also treated with FL with the same issue living in this house (see case 19BR004123). The owner also complained that FL PLUS DOG S and FL PLUS CATS were not effective (see cases 19BR004122 and 19BR004124). No further information is expected.
16-Sep-2019	UAE; 19BR004129; -; Brazil	Species: Feline Breed: Turkish Angora Sex: M Sex qualifier: Unknown Age: 3.00 Month(s) Weight: 1.2 kg	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	10-Sep-2019	10-Sep-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Pirulito, a male Angora of 3 months old and 1.2 kg, received FRONTLINE SPRAY 100 mL (FL) (002/18, Jun 2020, topical, neck and ampits – off-label use) for the first time, applied by the reporter on 10 Sep 2019 for flea treatment. Lack of efficacy was suspected because live fleas continued to be seen on the cat, so, on 16 Sep 2019 FL was administered once again, this time on the whole body, and Pirulito remains with fleas. He visualizes and removes 1 or 2 fleas daily and new fleas continue to appear. There are 1 cat and 1 dog living in the same household and they have been treated with Frontline® (pipette presentation – unsubstantiated) with no issue. Environment has been treated with unknown product. No further information is available.
17-Sep-2019	UAE; 19BR004130; SP; Brazil	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: M Sex qualifier: Unknown Age: 1.50 Year(s) Weight: 5.5 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	03-Sep-2019	15-Sep-2019*	12 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, a male crossbred cat of unknown name, 1.5 years old and 5.5 kg, received one pipette of FRONTLINE PLUS CATS (FL) (002/18B, exp date is unknown, topical, btw the shoulder blades) for the first time, administered by the reporter on 3 Sep 2019 for flea treatment. The cat started presenting fleas 1 month prior to NG. According to the reporter, FL was initially effective and it 'killed all the fleas', however, on date not informed (15 Sep 2019*) live fleas started to be found on the cat again so lack of efficacy is now suspected. There are an unknown number of untreated cats living in the same household. Environment not treated. No further information is available.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 68 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00075

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
18-Sep-2019	UAE; 19BR004133; SP; Brazil	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: M Sex qualifier: Unknown Age: 8.00 Month(s) Weight: 3.5 kg	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	03-Sep-2019	03-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner initially via retailer, 2 male crossbred cats of 3.5 kg (Coragem, 8 months old; Floquinho, 1 year old) received one pipette of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, base of skull) each, for the first time, administered by the reporter on 3 Sep 2019 for flea treatment. Lack of efficacy is suspected because live fleas continued to be found on the cats and they were also scratching themselves due to the infestation. So, on approx. 9 Sep 2019* Hectopar® was administered to Coragem and Floquinho and now they are no longer presenting fleas. The retailer informed that other customers also complained that FL was not effective but no details and valid patient info were provided. Environment has been treated with Butox® on 29 Aug 2019. There is a dog that was treated with FRONTLINE PLUS DOGS with the same issue living in this house (see case 19BR004134). No further information is available.
18-Sep-2019	UAE; 19BR004134; SP; Brazil	Species: Canine Breed: Yorkshire Terrier Sex: M Sex qualifier: Unknown Age: 4.00 Year(s) Weight: 4 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	03-Sep-2019	03-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner initially via retailer, Toy, a male Yorkshire Terrier of 4 years old and 4 kg, received one pipette of FRONTLINE PLUS DOGS S (FL) (lot and exp date are unknown, topical, base of skull) for the first time, administered by the reporter on 3 Sep 2019 for flea treatment. Lack of efficacy is suspected because the dog remained with fleas and also started to scratch himself due to the infestation. So, on approx. 9 Sep 2019* Hectopar® was administered to Toy and now he is no longer presenting fleas. The retailer informed that other customers also complained that FL was not effective but no details and valid patient info were provided. Environment was treated with Butox® on 29 Aug 2019. There are 2 cats that were treated with FRONTLINE PLUS CATS with the same issue living in this house (see case 19BR004133). No further information is available.
19-Sep-2019	UAE; 19BR004140; RJ; Brazil	Species: Canine Breed: Small crossbred (<10 Kg) Sex: M Sex qualifier: Unknown Age: 5.00 Month(s) Weight: 1.5 - 5 kg	2	2	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	10-Sep-2019	10-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, two male small crossbred dogs (Costela, 5 months old and around 1.5 kg; Torresmo, 5 kg and unknown age) were treated, for the first time, with FRONTLINE SPRAY 250 mL (FL) (lot and exp date are unknown, topical, back - incorrect application), applied by the reporter on 10 Sep 2019, for flea/tick treatment. The owner still sees ectoparasites on his dogs. Environment treated with Butox® every 6 months. No further information is available.
18-Sep-2019	UAE; 19BR004145; DF; Brazil	Species: Canine Breed: Siberian Husky Sex: M Sex qualifier: Unknown Age: 1.00 Year(s) Weight: 18.5 - 19 kg	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous	09-Sep-2019*	18-Sep-2019*	9 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, 2 dogs received FRONTLINE PLUS (unsubstantiated) (FL) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (1 Sep 2019*). The owner believes that FL is not working anymore. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided). This is the extent of the information available. UDPATE 24 SEP 2019 - The owner was contacted and reported that her two male Siberian Huskies (Joy, 1 year old and 19 kg; Nick, 3 years old and 18.5 kg) were treated with FL PLUS DOG M (lot and exp date

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 69 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00076

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Was the product used ok?: Yes					unknown, topical, btw the shoulder blades) around 15 days ago (9 Sep 2019*), for tick control. Lack of efficacy is suspected because a few ticks have been found on her dogs after treatment. It is unknown if the dogs currently have ticks. Environment not treated. FL has been applied every 3 months or so since date not specified. No further information is expected.
19-Sep-2019	UAE; 19BR004149; RJ; Brazil	Species: Canine Breed: Poodle (Miniature) Sex: F Sex qualifier: Unknown Age: 5.00 Year(s) Weight: 10 - 12 kg	2	2	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	01-Sep-2019	01-Sep-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, two female Poodles (Belinha, 12 kg, unknown age; Mel, 5 years old and 10 kg) were treated with FRONTLINE SPRAY 250 mL (FL) (004/18A, Sep 2020, topical, parts of the body - low dose), applied by the reporter daily since 1 Sep 2019, for flea treatment. Lack of efficacy is suspected because the animals remain with fleas. Environment was not treated and FL was applied on the carpet. There is a cat treated with FL with the same issue living in this house (see case 19BR004150). In addition, the owner also complained that FL is odorless (TPC reported on GOT - PRID 497894). Human exposure reported on 19BR004151. No further information is expected.
19-Sep-2019	UAE; 19BR004150; RJ; Brazil	Species: Feline Breed: Persian (No Further Description) Sex: M Sex qualifier: Unknown Age: 6.00 Year(s) Weight: 3 kg	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	01-Sep-2019	01-Sep-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Mutufo, a male Persian of 6 years old and 3 kg, was treated with FRONTLINE SPRAY 250 mL (FL) (004/18A, Sep 2020, topical, parts of the body - low dose), applied by the reporter daily since 1 Sep 2019, for flea treatment. Lack of efficacy is suspected because the animal remains with fleas. Environment was not treated and FL was applied on the carpet. There are 2 dogs treated with FL with the same issue living in this house (see case 19BR004149). In addition, the owner also complained that FL is odorless (TPC reported on GOT - PRID 497894). Human exposure reported on 19BR004151. No further information is expected.
19-Sep-2019	UAE; 19BR004163; MG; Brazil	Species: Canine Breed: Medium crossbred (10 - 20 Kg) Sex: F Sex qualifier: Unknown Age: 2.00 Year(s) Weight: 15 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	2019*	30-Aug-2019*	17 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Laila, a female crossbred dog of 2 years old and 15 kg, received one pipette of FRONTLINE PLUS DOGS M (FL) (lot and exp date are unknown, topical, back) administered by the reporter on 13 Aug 2019 for ectoparasite control. Lack of efficacy is suspected because approx. 15-20 days post FL application (30 Aug 2019*) live fleas started to be found on the dog. FL has been administered every 3 months with no issue (1st administration date was not informed). The dog has outdoor access. Environment not treated. No further information is available.
19-Sep-2019	UAE; 19BR004170; SP; Brazil	Species: Feline Breed: Feline (unknown) Sex: X Sex qualifier:	18	18	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON	04-Sep-2019	04-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, 21 cats of unknown signalment were treated with FRONTLINE (unsubstantiated) (FL) (lot, exp date, route and location are unknown), applied by the reporter on 4 Sep 2019. 15 days post product application, the owner still sees fleas on her

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 70 of 867

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00077

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Unknown Age: 6.00 Month(s) Weight: 1 - 4.5 kg*				Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes					animals. This is the extent of the information available. UPDATE 21 Oct 2019 – The pet owner was contacted and reported that 18 cats (mixed, from approx. 6 months to 8 years old and 900 g to 4.5 kg) received one pipette FRONTLINE SPOT-ON CATS (FL) (topical, btw the shoulder blades) for flea treatment. Lack of efficacy is still suspected because the animals remain with fleas. FL has been administered in the past (dose frequency and 1st adm date not provided) with no issue. Environment not treated. Similar case reported on 19BR004864. No further information is available.
18-Sep-2019	UAE; 19BR004181; -; Brazil	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	7	7	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	01-Sep-2019*	01-Sep-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, 7 dogs were treated with FRONTLINE (FL) (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (1 Sep 2019*), for flea treatment. The animals remain with fleas. There are also cats treated with FL with the same issue living in this house (see case 19BR004182). No further information is available.
18-Sep-2019	UAE; 19BR004182; -; Brazil	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	01-Sep-2019*	01-Sep-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, an unknown number of cats were treated with FRONTLINE (FL) (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (1 Sep 2019*), for flea treatment. The animals remain with fleas. FL was used in the past with no issue (dose frequency is unknown and date of first administration was not provided). There are also dogs that were treated with FL with the same issue living in this house (see case 19BR004181). No further information is available.
20-Sep-2019	UAE; 19BR004191; SP; Brazil	Species: Canine Breed: Canine various breeds Sex: F Sex qualifier: Unknown Age: 6.00 Month(s) Weight: 2.5 - 18 kg	3	3	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	16-Sep-2019	16-Sep-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, three female dogs between 6 months old to 10 years old, 2.5 kg to 18 kg, were treated with FRONTLINE SPRAY 100 mL (FL) (lot and exp date are unknown, topical, ear and tail - incorrect application), applied by the reporter on 16 Sep 2019 and 18 Sep 2019, for flea/tick treatment. Lack of efficacy is suspected because fleas and live ticks have been found on her animals. Environment treated with deltamethrin. No further information is expected.
20-Sep-2019	UAE; 19BR004192; MG; Brazil	Species: Feline Breed: Siamese Sex: F Sex qualifier: Unknown	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other	20-Sep-2019*	20-Sep-2019*	0 Day(s)	D-D	Suspected Adverse Event: As reported by the pet owner, Pity, a female Siamese cat of approx. 6.5 years old and unknown weight, received FRONTLINE SPRAY 100 ML (FL) (002/18, exp date is unknown, topical, whole body) administered by the reporter on 20 Sep 2019* (estimated) for itching treatment. Pity was in good

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 71 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00078

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: 6.50 Year(s) Weight: Unknown				products Route: Topical / Cutaneous Was the product used ok?: No (Indication not indicated / recommended)					health prior to the application. An unknown time after FL Pity's back skin contracted. The pet owner used a damp cloth to remove the product from the cat and the sign was no longer seen. FL has been administered in the past (dose frequency and 1st administration date not informed) with no issue. There is no history of AEs to other products. No further information is available.
23-Sep-2019	UAE; 19BR004200; SP; Brazil	Species: Feline Breed: Feline various breeds Sex: M Sex qualifier: Unknown Age: 10.00 Year(s) Weight: 4 - 5 kg	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	20-Sep-2019	20-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, two male mixed breed cats (Boris, 14 years old and around 5 kg; Balman, 10 years old and 4 kg), were treated with one vial of FRONTLINE PLUS CATS (FL) (007/18B; unknown exp date, topical, btw the shoulder blades) each, applied by the reporter on 20 Sep 2019, for flea treatment. Lack of efficacy is suspected because the pets remain with fleas. Environment treated with deltamethrin. FL was applied years ago. No further information is expected.
21-Sep-2019	UAE; 19BR004201; SP; Brazil	Species: Canine Breed: Small crossbred (<10 Kg) Sex: F Sex qualifier: Unknown Age: 3.00 Year(s) Weight: 8 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	13-Sep-2019	13-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, one female dog (other signalment is unknown) was treated with FRONTLINE PLUS (FL) (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on 13 Sep 2019, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. In addition, the pet is scratching itself due to fleas. This is the extent of the information available. UPDATE 25 SEP 2019 - Kiki, a female small crossbred dog of 3 years old and 8 kg, was treated, for the first time, with one vial of FL PLUS DOG S (topical, btw the shoulder blades). Kiki is bathed every 15 days and started presenting fleas over a month prior to FL. The pet remains with fleas. Environment not treated. No further information is expected.
21-Sep-2019	UAE; 19BR004202; BA; Brazil	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: M Sex qualifier: Unknown Age: 10.00 Year(s) Weight: 6 kg	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	17-Sep-2019	17-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Bublack, a male Domestic Shorthair cat (crossbred) of 10 years and 6 kg, received one pipette of FRONTLINE SPOT-ON CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades) administered by the reporter on 17 Sep 2019 for flea treatment. Lack of efficacy is suspected because Bublack remains with live fleas and he is scratching himself due to the ectoparasite infestation. It is unknown if FL has been administered in the past. The reporter added that Bublack used to receive Fiprolax® 'since always' (dose frequency not informed) with good results. Environment not treated. No further information is available.
21-Sep-2019	UAE; 19BR004204; SP; Brazil	Species: Canine Breed: Retriever (Golden) Sex: M Sex qualifier: Unknown Age: 2.00 Year(s) Weight: 37 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical /	11-Sep-2019	21-Sep-2019	10 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, a dog of unknown signalment received FRONTLINE PLUS DOGS L (FL) (lot, exp date, route and location are unknown) for the first time, applied by the reporter on 11 Sep 2019 for flea treatment. Lack of efficacy is suspected because on 21 Sep 2019 2 live fleas were found on the dog. The dog is bathed at home every 15 days. Environmental factors are not known. This is the extent of the information available for now. UPDATE 25 Sep 2019 - The pet owner was contacted and reported that Theo, a male

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 72 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00079

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Cutaneous Was the product used ok?: Yes					Golden Retriever of 2 years old and 37 kg, received one pipette of FL (topical, btw the shoulder blades) for the first time. Lack of efficacy is suspected because live fleas are still being found on the dog. Environment treated with unknown product. No further information is available.
24-Sep-2019	UAE; 19BR004226; SP; Brazil	Species: Canine Breed: Pinscher (Miniature) Sex: F Sex qualifier: Unknown Age: 3.00 Year(s) Weight: 4 - 5 kg	2	2	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	Jun-2019*	Jun-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 2 female Pinschers (Pipoca, 7 years old, 5kg; Lili, 3 years old, 4 kg) received FRONTLINE SPRAY 250 mL (FL) (lot and exp date are unknown, topical, whole body) each, for the first time, applied by the reporter on Jun, Jul* and 21 Sep 2019 for flea treatment. Lack of efficacy is suspected because the pets remain with live fleas. Environment not treated. There is a cat that was treated with FL with the same issue living in this house (see case 19BR004227). No further information is available.
24-Sep-2019	UAE; 19BR004227; SP; Brazil	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: F Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	Jun-2019*	Jun-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Lola, a female Domestic Shorthair cat (crossbred) of 4 months old and unknown weight, received FRONTLINE SPRAY 250 mL (FL) (lot and exp date are unknown, topical, whole body) for the first time, applied by the reporter on Jun, Jul and 21 Sep 2019 for flea treatment. Lack of efficacy is suspected because the pet remains with live fleas. Environment not treated. There are 2 dogs that were treated with FL with the same issue living in this house (see case 19BR004226). No further information is available. UPDATE 25 SEP 2019 - The owner forgot to mention that she also applied FL on her another cat (Preta, female). Both cats remain with fleas. No further information is expected.
24-Sep-2019	UAE; 19BR004230; SP; Brazil	Species: Canine Breed: Chowchow Sex: F Sex qualifier: Unknown Age: 14.00 Year(s) Weight: 15 kg	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	12-Sep-2019	12-Sep-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Sissy, a female Chow Chow of 14 years old and 15 kg, was treated, for the first time, with FRONTLINE SPRAY 100 mL (FL) (002/18A, Jun 2020, topical, back and belly - incorrect application/low dose), applied by the reporter on 12 Sep 2019, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. Environment not treated. There are 2 cats that were treated with FL with the same issue living in this house (see case 19BR004231). TPC reported on GOT (PRID 500766). No further information is expected.
24-Sep-2019	UAE; 19BR004231; SP; Brazil	Species: Feline Breed: Feline various breeds Sex: X Sex qualifier: Unknown Age: 8.00 Month(s) Weight: 2.5 - 3 kg	2	2	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment /	12-Sep-2019	12-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, two mixed breed cats (Pandora, female, 8 months old, 2.5 kg; Falsca, male 13 months old and 3 kg), were treated, for the first time, with FRONTLINE SPRAY (FL) (002/18A, Jun 2020, topical, back and belly - incorrect application/low dose), applied by the reporter on 12 Sep 2019, for flea treatment. Lack of efficacy is suspected because the animals remain with fleas. Environment not treated. There is a dog that was treated with FL with the same issue living in this house (see case 19BR004230). TPC reported on GOT (PRID 500766). No further information is expected.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 73 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00080

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						vaccination program not respected)					
24-Sep-2019	UAE; 19BR004245; RJ; Brazil	Species: Feline Breed: Feline various breeds Sex: M Sex qualifier: Unknown Age: 3.00 Year(s) Weight: 3 kg	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	10-Sep-2019	10-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Bils, a male mixed breed cat of 3 years old and 3 kg, was treated, for the first time, with FRONTLINE SPRAY 250 mL (FL) (001/19A, unknown exp date, topical, parts of the body - incorrect application), applied by the reporter on 10 Sep 2019, for flea/tick treatment. Lack of efficacy is suspected because the pet remains with a high quantity of fleas and ticks. Environment treated with an unknown product. There is a dog that was treated with FL with the same issue living in this house (see case 19BR004246). No further information is expected.
24-Sep-2019	UAE; 19BR004246; RJ; Brazil	Species: Canine Breed: Pinscher (Miniature) Sex: F Sex qualifier: Unknown Age: 6.00 Month(s) Weight: 2 kg	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	10-Sep-2019	10-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Mel, a female Pinscher of 6 months old and 2 kg, was treated, for the first time, with FRONTLINE SPRAY 250 mL (FL) (001/19A, unknown exp date, topical, parts of the body - incorrect application), applied by the reporter on 10 Sep 2019, for flea/tick treatment. Lack of efficacy is suspected because the pet remains with a high quantity of fleas and ticks. Environment treated with an unknown product. There is a cat that was treated with FL with the same issue living in this house (see case 19BR004245). No further information is expected.
23-Sep-2019	UAE; 19BR004253; SP; Brazil	Species: Canine Breed: Yorkshire Terrier Sex: M Sex qualifier: Unknown Age: 7.00 Year(s) Weight: 3.5 kg	2	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	17-Sep-2019	23-Sep-2019*	6 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Aufonso, a male Yorkshire of 7 years old and 3.5 kg, was treated, for the first time with FRONTLINE SPRAY (FL) (005/18A, Sep 2020, topical, whole body), applied by the reporter on 17 Sep 2019, for flea and tick prevention. Lack of efficacy is suspected because one tick was found on her dog. Currently, the dog is free of ticks. The dog is bathed weekly and has access to the street. Environment not treated. There is one more dog in this household that was treated with FL and it has no issue. No further information is expected.
23-Sep-2019	UAE; 19BR004254; SP; Brazil	Species: Canine Breed: Pug Sex: M Sex qualifier: Unknown Age: 70.00 Day(s) Weight: 1.2 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the	23-Sep-2019	23-Sep-2019	8 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, one dog of 70 days old (other signalment is unknown) was treated, for the first time, with FRONTLINE PLUS (FL) (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on 15 Sep 2019, for flea treatment. On 23 Sep 2019, the owner noticed more than 8 fleas on her dog. No further information is expected. UPDATE 30 Sep 2019 – The pet owner was contacted and reported that Zeca, a male Pug of 70 days old and 1.2 kg, received one pipette of FRONTLINE PLUS DOGS S (FL) (topical, btw the shoulder blades) for the first time on 23 Sep 2019. It is unknown if fleas are still being found on the animal.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 74 of 867

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

v1.2

ED_005739D_00014390-00081

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						product used ok?: Yes					Environment has not been treated. No further information is available.
22-Sep-2019	UAE; 19BR004257; SP; Brazil	Species: Canine Breed: Yorkshire Terrier Sex: F Sex qualifier: Unknown Age: 4.00 Year(s) Weight: 2.5 - 4 kg	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	19-Sep-2019	22-Sep-2019	3 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, two female Yorkies (Belinha, 6.5 years old and 4 kg; July, 4 years old and 2.5 kg), were treated with one vial of FRONTLINE PLUS DOG S (FL) (022/18B, May 2020, topical, btw the shoulder blades), applied by the reporter on 19 Sep 2019, for flea treatment. Lack of efficacy is suspected because the owner still sees fleas on her dogs. Environment treated with FL SPRAY and Butox®. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided). The animals have no outdoor access, but sometimes they have access to the front yard. On 22 Sep 2019, one tablet of NEXGARD (11.3 mg) was given to each dog and they are currently free of fleas. However, one of them is still scratching herself (see case 19BR004258). No further information is available.
23-Sep-2019	UAE; 19BR004264; SP; Brazil	Species: Feline Breed: Feline (various breeds) Sex: M Sex qualifier: Unknown Age: 7.00 Year(s) Weight: 3.5 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	10-Aug-2019*	01-Sep-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Gato, a male mixed breed cat of 7 years old and 3.5 kg, was treated with one vial of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter around 10 Aug 2019 for flea control. Lack of efficacy is suspected because fleas started to be found on her pet after treatment, so another application of FL was made on 7 Sep 2019 and the cat remained with fleas. Environment treated with Butox®. The animal has outdoor access. The owner applied another flea preventative product on 25 Sep 2019 and started to see dead fleas. However, it is unknown if the pet is currently free of fleas. FL has been applied every 2 months with no issue for the last 6 years (since 2013*). No further information is expected.
25-Sep-2019	UAE; 19BR004268; SP; Brazil	Species: Canine Breed: Lhasa Apso Sex: M Sex qualifier: Unknown Age: 9.00 Year(s) Weight: 14 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	15-Jan-2019*	25-Sep-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Melk Bonive, a male Lhasa Apso of 9 years old and 14 kg, was treated with one vial of FRONTLINE SPOT-ON DOG M (FL) (lot and exp date are unknown, topical, unknown location), applied by the reporter on 15 Sep 2019, for flea/tick prevention. Lack of efficacy is suspected because the pet got ticks during a walk after treatment. It is unknown if the dog remains with ticks. The reporter used a hair dryer to 'dry' the product after application. Environment not treated. FL has been applied monthly since date not specified (15 Jan 2019*). No further information is expected.
24-Sep-2019	UAE; 19BR004276; -, Brazil	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: 2.00 Month(s) Weight: Unknown	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No	23-Sep-2019	24-Sep-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, a cat of 2 months old received FRONTLINE SPRAY 100 ML (FL) (lot and exp date are unknown, topical, back; off-label use) for the first time, applied by the reporter on 23 Sep 2019 for flea treatment. Lack of efficacy is suspected because live fleas are being found on the pet after treatment. Environmental factors are unknown. No further information is available.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 75 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00082

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						(Treatment / vaccination program not respected)					
24-Sep-2019	UAE; 19BR004281; SP; Brazil	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: M Sex qualifier: Unknown Age: 3.00 Year(s) Weight: 6.3 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	17-Sep-2019	17-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Guri, a male Domestic Shorthair cat (crossbred) of 3 years old and 6.3 kg, received one pipette of FRONTLINE PLUS CATS (FL) (lot and exp date is unknown, topical, btw the shoulder blades) for the first time, administered by the reporter on 17 Sep 2019 for flea treatment. She added that FL was also administered to the animal because 'he has flea disease' (unspecified). Lack of efficacy is suspected because live fleas are still being found on the cat. Guri is bathed weekly and has outdoor access. According to the reporter, he has frequent contact with untreated flea-infested cats and also has contact with a Brazilian monkey species (sagui). Indoor environment is treated with K-Othrine®. No further information is available.
24-Sep-2019	UAE; 19BR004283; SP; Brazil	Species: Canine Breed: Medium crossbred (10 - 20 Kg) Sex: X Sex qualifier: Unknown Age: 7.00 Year(s) Weight: 11.5 - 12.3 kg	3	3	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	23-Sep-2019	23-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 3 crossbred dogs (Cassias, male, 10 years old, approx. 12.3 kg; Brenda, female, 7 years old, approx. 11.5 kg; Belinha, female, 9 years old, 11.5 kg) received one pipette of FRONTLINE SPOT-ON DOGS M (FL) (lot and exp date are unknown, topical, btw the shoulder blades) each, administered by the reporter on 23 Sep 2019 for flea treatment. Lack of efficacy is suspected because live fleas are still being found on the dogs. The dogs use to be bathed approx. every 15 days. FL has been administered in the past (dose frequency and 1st adm date not informed) with no issue. There are 2 cats of the same household and they have been simultaneously treated with an unknown topical product. Environment treated with Butox®. No further information is available.
24-Sep-2019	UAE; 19BR004289; -; Brazil	Species: Feline Breed: Feline (unknown) Sex: F Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	01-Sep-2019*	01-Sep-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, one female cat of unknown signalment received FRONTLINE PLUS (FL) (unsubstantiated) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (1 Sep 2019*). The owner believes that FL is not working. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided). No further information is available.
26-Sep-2019	UAE; 19BR004293; SC; Brazil	Species: Feline Breed: Feline various breeds Sex: F Sex qualifier: Unknown Age: 1.00 Year(s) Weight: 4.8 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used	21-Sep-2019	21-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Celina, a female mixed breed cat of 1 year old and 4.8 kg, was treated, for the first time, with one vial of FRONTLINE PLUS CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 21 Sep 2019, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. Environment treated with an unknown product. There is a dog treated with FRONTLINE with the same issue living in this house (see case 19BR004294). No further information is expected.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 76 of 867

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00083

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
24-Sep-2019	UAE; 19BR004294; SC; Brazil	Species: Canine Breed: Small crossbred (<10 Kg) Sex: M Sex qualifier: Unknown Age: 3.00 Year(s) Weight: 5.2 kg	1	1	0	ok?: Yes Product used: FIPRONIL SPOT ON DOG Other products used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON; Route: Topical / Cutaneous Was the product used ok?: Yes	14-Sep-2019	14-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Bebe, a male small crossbred dog of 3 years old and 5.2 kg, was treated, for the first time, with one vial of FRONTLINE SPOT-ON DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 14 Sep 2019, for flea treatment. Fleas have been found on her dog. So, on 21 Sep 2019, the owner applied one vial of FL PLUS DOG S (lot and exp date are unknown, topical, btw the shoulder blades). The pet remains with fleas. Environment treated with an unknown product. There is a cat treated with FRONTLINE PLUS CAT with the same issue living in this house (see case 19BR004293). No further information is expected.
25-Sep-2019	UAE; 19BR004295; SP; Brazil	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: F Sex qualifier: Unknown Age: 5.00 Year(s) Weight: 6 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	18-Sep-2019	18-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Guta, a female Domestic Shorthair cat (crossbred) of 5 years old and 6 kg, received one pipette of FRONTLINE PLUS CATS (FL) (lot and exp date is unknown, topical, from base of skull to the back) administered by the reporter on 18 Sep 2019 for flea treatment. Lack of efficacy is suspected because the cat remains with live fleas. Fleas are mostly seen on her face. FL has been administered approx. every 1 year (last application on Nov 2018; 1st adm date were not provided) with no issue. Environment treated with K-Othrine®. No further information is available.
25-Sep-2019	UAE; 19BR004297; SP; Brazil	Species: Canine Breed: Medium crossbred (10 - 20 Kg) Sex: F Sex qualifier: Unknown Age: 12.00 Year(s) Weight: 12 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	28-Aug-2019	11-Sep-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Brisa, a female crossbred dog of 12 years old and 12 kg, received one pipette of FRONTLINE PLUS DOGS M (FL) (lot and exp date are unknown, topical, btw the shoulder blades) administered by the reporter on 28 Aug 2019 for tick treatment. Lack of efficacy is suspected because since 11 Sep 2019 ticks returned to be found on the dog. FL has been administered in the past (1st administration date and dose frequency were not informed) with no issue. According to the reporter, Brisa lives in a house of a family member and she is not sure if the pet may have been bathed after FL application. Environment not treated. No further information is available.
26-Sep-2019	UAE; 19BR004298; RJ; Brazil	Species: Canine Breed: Yorkshire Terrier Sex: F Sex qualifier: Unknown Age: 3.00 Year(s) Weight: 3.2 - 3.5 kg	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment /	01-Sep-2019*	01-Sep-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, two Yorkies (Kiki, a female of 3 years old and 3.2 kg; Mole, a female of 8 years old and 3.5 kg), were treated with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied to each one by the reporter around 1 Sep 2019 and around 20 Sep 2019, for flea treatment. Lack of efficacy is suspected because the animals remain with fleas. Environment not treated. No further information is expected.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 77 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

v1.2

ED_005739D_00014390-00084

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						vaccination program not respected)					
25-Sep-2019	UAE; 19BR004300; SP; Brazil	Species: Feline Breed: Persian (No Further Description) Sex: F Sex qualifier: Unknown Age: 6.50 Year(s) Weight: 3 kg	1	1	0	Product used: FIPRONIL SPRAY Other products used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON; Route: Topical / Cutaneous Was the product used ok?: Yes	28-Aug-2019	28-Aug-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Nina, a female Persian cat of 6.5 years old and 3 kg, received FRONTLINE SPRAY 100 mL (FL) (002/18B, exp date is unknown, topical, whole body) for the first time, applied by the reporter on 28 Aug 2019 for flea treatment. Lack of efficacy is suspected because live fleas continued to be seen on the cat, so, on 4 Sep 2019 one pipette of FRONTLINE PLUS CATS (FL) (FL PLUS) (004/18A, exp date is unknown, topical, back) was administered and fleas are still being found on Nina. FL PLUS has been administered in the past (dose frequency and 1st adm date not provided) with no issue. Nina has no outdoor access. Environment treated with Butox® and K-Othrine®. No further information is available.
26-Sep-2019	UAE; 19BR004313; -, Brazil	Species: Canine Breed: Poodle (Miniature) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	01-Jan-2019*	01-Jan-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, one Mini Poodle of unknown signalment was treated with one vial of FRONTLINE SPOT-ON DOG S (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on date not specified (1 Jan 2019*). The product was not effective. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided). FL was used again a few months later (Sep 2019) for tick treatment and the dog remained with ticks (see case 19BR004314). No further information is available.
26-Sep-2019	UAE; 19BR004314; -, Brazil	Species: Canine Breed: Poodle (Miniature) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	01-Sep-2019*	26-Sep-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, one Mini Poodle of unknown signalment was treated with one vial of FRONTLINE SPOT-ON DOG S (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 1 Sep 2019*, for tick treatment. The owner believes that FL is not working because his pet still has ticks. Lack of efficacy of the previous administration of FL is also suspected (see case 19BR004313). FL was used in the past with no issue (dose frequency and date of first administration are unknown). No further information is available.
27-Sep-2019	UAE; 19BR004324; PR; Brazil	Species: Canine Breed: Lhasa Apso Sex: F Sex qualifier: Unknown Age: 9.00 Year(s) Weight: 7 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	04-Sep-2019*	04-Sep-2019*	3 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, one female Lhasa Apso of unknown signalment was treated with FRONTLINE PLUS (unsubstantiated) (FL) (lot, exp date, route and location are unknown), applied by the reporter on date not specified (1 Sep 2019 - chosen at random), for flea/tick control. Lack of efficacy is suspected because the pet has live ticks. The dog has access to the street and gets ticks during her walks. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided). This is the extent of the information available. UPDATE 4 Oct 2019 – The pet owner was contacted and reported that July, a female Lhasa Apso of 9 years old and 7 kg, received FRONTLINE PLUS DOGS S (topical, base of skull and btw the shoulder blades) on approx. 4 Sep 2019. July is usually taken for walking outdoors 3 times a day. The

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 78 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

v1.2

ED_005739D_00014390-00085

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											reporter added that she manually removes the ticks from July and the dog is no longer presenting ectoparasites. Environment not treated. A SAE case involving the same patient was reported on 19BR004772. No further information is available.
26-Sep-2019	UAE; 19BR004330; DF; Brazil	Species: Canine Breed: Dachshund Sex: M Sex qualifier: Unknown Age: 1.00 Year(s) Weight: 5 - 6 kg	2	2	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	22-Aug-2019	22-Aug-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, two dogs of unknown signalment were treated with FRONTLINE SPRAY (004/18, Sep 2020, route and location are unknown), applied by the reporter on date not specified (1 Sep 2019*), for flea treatment. Lack of efficacy is suspected because the animals remained with fleas, so another application of FL was made 2 weeks later (15 Sep 2019*) and the pets remain with fleas. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided). There is a cat that was treated with FL with the same issue living in this house (see case 19BR004331). No further information is available. UPDATE 7 OCT 2019 - The owner was contacted and reported that her two male Dachshunds (Brad Pitt, 10 years old and 6 kg; Doritos, 1 year old and 5 kg) were treated with FRONTLINE SPRAY 250 mL (topical, whole body), applied by the reporter on 22 Aug 2019 and 14 Sep 2019, for flea treatment. The number of fleas has decreased, however, the owner still sees fleas on her animals. Environment not treated. FL was applied in the past with no issue (every 6 months since date not specified). No further information is expected.
26-Sep-2019	UAE; 19BR004331; DF; Brazil	Species: Feline Breed: Feline crossbred Sex: M Sex qualifier: Unknown Age: 2.00 Year(s) Weight: 2.5 kg	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	22-Aug-2019	22-Aug-2019	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via e-mail, one cat of unknown signalment received FRONTLINE SPRAY (004/18, Sep 2020, route and location are unknown), applied by the reporter on date not specified (1 Sep 2019*), for flea treatment. Lack of efficacy is suspected because the animal remained with fleas, so another application of FL was made 2 weeks later (15 Sep 2019*) and the pet remains with fleas. FL was applied in the past with no issue (dose frequency is unknown and first application was not provided). There are 2 dogs that were treated with FL with the same issue living in this house (see case 19BR004330). No further information is available. UDPATE 7 OCT 2019 - The owner was contacted and reported that Chantilly, a male mixed breed cat of 2 years old and 2.5 kg, was treated with FRONTLINE SPRAY 250 mL (topical, whole body), applied by the reporter on 22 Aug 2019 and 14 Sep 2019, for flea treatment. The number of fleas has decreased, however, the owner still sees fleas on her pet. Environment not treated. FL was applied in the past with no issue (every 6 months since date not specified). No further information is expected.
27-Sep-2019	UAE; 19BR004337; MG; Brazil	Species: Canine Breed: Shih Tzu Sex: M Sex qualifier: Unknown Age: 5.00 Year(s) Weight: 5 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	26-Sep-2019	26-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Theo, a male Shih Tzu of 5 years old and 5 kg received one pipette of FRONTLINE DOGS S (FL) (unsubstantiated; lot, exp date, route and location are unknown) for the first time, administered by an unknown person on 26 Sep 2019 for flea treatment. Lack of efficacy is suspected because the pet remains with live fleas. The dog is usually bathed every 15 days in a retail shop highly frequented by other dogs and cats. There is an untreated non-infested dog living in the same household. Environment not treated. There is another dog that was treated with FL with the same issue living in this house (see case 19BR004338). No further information is available.

N/A signifies the information for this field is either not available or not applicable

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

Report printed on 25-Oct-2019 at 8:39:59PM

*indicates Approximate date or weight

Page 79 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00086

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
27-Sep-2019	UAE; 19BR004338; MG; Brazil	Species: Canine Breed: Terrier Breeds (500 Series) Sex: M Sex qualifier: Unknown Age: 8.00 Year(s) Weight: 6.5 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	26-Sep-2019	26-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Faisca, a male Brazilian Terrier of 8 years old and approx. 6.5 kg received one pipette of FRONTLINE (FL) (unsubstantiated) (lot, exp date, route and location are unknown) for the first time, administered by an unknown person on 26 Sep 2019 for flea treatment. Lack of efficacy is suspected because the pet remains with live fleas. The dog is bathed every 15 days in a retail shop highly frequented by other dogs and cats. There is an untreated non-infested dog living in the same household. Environment not treated. There is another dog that was treated with FL with the same issue living in this house (see case 19BR004337). No further information is available.
27-Sep-2019	UAE; 19BR004343; SP; Brazil	Species: Canine Breed: Spaniel (Cocker) Sex: M Sex qualifier: Unknown Age: 3.00 Year(s) Weight: 8 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	11-Sep-2019	11-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Sheik, a male Cocker of 3 years old and 8 kg, received 1 dose of FRONTLINE PLUS DOG S (lot and exp date unknown, topical, btw the shoulder blades) for the first time, administered by the reporter on 11 Sep 2019 for flea treatment. The dog started presenting fleas 2 months prior to FL. Lack of efficacy is suspected because the pet remains with fleas. Environment not treated. NEXGARD was used in the past with no issue. No further information is available.
27-Sep-2019	UAE; 19BR004347; MG; Brazil	Species: Canine Breed: Yorkshire Terrier Sex: M Sex qualifier: Unknown Age: 6.00 Year(s) Weight: 9 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	2018*	27-Sep-2019	9 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Nero, a male Yorkshire of 6 years old and 9 kg, received FRONTLINE PLUS DOG M (005/18A, exp date Jan 2020, topical, btw the shoulder blades), administered by the reporter on 18 Sep 2019 for flea and tick prevention. Lack of efficacy is suspected because 2 fleas were found and removed from the dog on 27 Sep 2019. This dog does not have access to the street. FL was used in the past with no issue (dose frequency - 3 months, date of first administration was not provided - 2018*). There is a dog that was treated with FL with no issue living in this house. The environment has not been treated. No further information is available.
27-Sep-2019	UAE; 19BR004349; RS; Brazil	Species: Canine Breed: Spaniel (Cocker) Sex: F Sex qualifier: Unknown Age: 21.00 Month(s) Weight: 10.5 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	05-Sep-2019	05-Sep-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Dolores, a female Cocker Spaniel of 21 months old and 10.5 kg, received one pipette of FRONTLINE PLUS DOGS M (FL) (020/18A, exp date is unknown, topical, btw the shoulder blades) for the first time, administered by the reporter on 5 Sep 2019 for flea treatment. Lack of efficacy is suspected because the pet remains with live fleas. According to the reporter, 'some people have said that FL is not effective', however, details and valid patient info were not provided. Environment not treated. No further information is available.
27-Sep-2019	UAE; 19BR004350; SP; Brazil	Species: Canine Breed: Canine various breeds Sex: X	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE	20-Sep-2019*	20-Sep-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pets owner, 2 dogs (mixed, 2.5 to 17 years old and 40 kg) received 1 dose of FRONTLINE PLUS DOG L (FL) (lot and exp date unknown, topical, btw the shoulder blades) each, administered by the

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 80 of 867

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00087

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: Unknown Age: 2.50 Year(s) Weight: 40 kg				9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes					reporter around 2 weeks ago (20 Sep 2019*) for flea treatment. Lack of efficacy is suspected because the pets remain with fleas . FL was used in the past with no issue (dose frequency is unknown and date of first administration was not provided). There are 2 other dogs that were treated with FL with the same issue living in this household (see case 19BR004351). The dogs live in a country house and have outdoor access. However, they do not have contact with other dogs. Part of the environment is treated with K-Othrine® and blowtorch. No further information is available.
27-Sep-2019	UAE; 19BR004351; SP; Brazil	Species: Canine Breed: Canine various breeds Sex: X Sex qualifier: Unknown Age: 2.50 Year(s) Weight: 50 - 60 kg	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	20-Sep-2019*	20-Sep-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pets owner, 2 dogs (mixed, 2.5 to 5 years old and 50 to 60 kg) received 1 dose of FRONTLINE PLUS DOG XL (FL) (lot and exp date unknown, topical, btw the shoulder blades) each, administered by the reporter around 2 weeks ago (20 Sep 2019*) for flea treatment. Lack of efficacy is suspected because the pets remain with fleas . FL was used in the past with no issue (dose frequency is unknown and date of first administration was not provided). There are 2 other dogs that were treated with FL with the same issue living in this household (see case 19BR004350). The dogs live in a country house and have outdoor access. However, they do not have contact with other dogs. Part of the environment is treated with K-Othrine® and blowtorch. No further information is available.
25-Sep-2019	UAE; 19BR004363; -; Brazil	Species: Canine Breed: Yorkshire Terrier Sex: F Sex qualifier: Unknown Age: 5.00 Year(s) Weight: 2.5 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	01-Jan-2018*	10-Jan-2018*	9 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner via social media, one female dog of unknown signalment received FRONTLINE (unsubstantiated) (lot, exp date, route and administration site unknown), administered by the reporter on date not specified (1 Jan 2018*) for flea and tick prevention. Lack of efficacy is suspected because the pet got fleas after treatment . In addition, the pet has flea allergy dermatitis. FL was given in the past with no issue (dose frequency is unknown and first administration was not provided). Related cases regarding suspected lack of efficacy of NEXGARD were reported on 19BR004236 and 19BR004259. This is the extent of the information available. UPDATE 27 SEP 2019 - Estopinha, a female Yorkshire of 5 years old and 2.5 kg was treated with FL, but there is no further information regarding this case.
30-Sep-2019	UAE; 19BR004372; SP; Brazil	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: F Sex qualifier: Unknown Age: 7.00 Month(s) Weight: 2 kg	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	23-Sep-2019*	24-Sep-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Antonia, a female Domestic Shorthair cat (crossbred) of 7 months old and 2 kg, received FRONTLINE SPRAY 250 ML (FL) (004/18, exp date is unknown, topical, whole body) applied by the reporter on approx. 23 Sep 2019* for flea treatment. According to the reporter, on 23 Sep 2019* the pet stopped scratching herself, however, since 24 Sep 2019* itching returned to be experienced by Antonia and since 26 Sep 2019* fleas returned to be found. There was a decrease on the quantity of fleas, however, they are still being seen. FL has been administered only once in the past (date not informed) with no issue. Environment treated with unknown product. There are 3 dogs that were treated with FL with the same issue living in this house (see case 19BR004373). No further information is available.
30-Sep-2019	UAE; 19BR004373; SP; Brazil	Species: Canine Breed: Canine various breeds Sex: X Sex qualifier:	3	3	0	Product used: FIPRONIL SPRAY Other products used: no other	23-Sep-2019*	24-Sep-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 3 dogs (Rodolfo, male, crossbred, 13 years old, 13 kg; Julia, female, crossbred, 3 years old, 5 kg; Joaquim, Dachshund, 9 years old, 8 kg) received FRONTLINE SPRAY 250 ML (FL) (004/18, exp date is unknown, topical, whole body) applied by the reporter on approx.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 81 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00088

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Unknown Age: 3.00 Year(s) Weight: 5 - 13 kg				products Route: Topical / Cutaneous Was the product used ok?: Yes					23 Sep 2019* for flea treatment. According to the reporter, on 23 Sep 2019* the pets stopped scratching themselves, however, since 24 Sep 2019* itching returned to be experienced by the dogs and since 26 Sep 2019* fleas returned to be found. There was a decrease on the quantity of fleas, however, they are still being seen. FL has been administered only once in the past (date not informed) with no issue. Environment treated with unknown product. There is a cat that was treated with FL with the same issue living in this house (see case 19BR004372). No further information is available.
30-Sep-2019	UAE; 19BR004380; SP, Brazil	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: X Sex qualifier: Unknown Age: 2.00 Year(s) Weight: 3 - 4 kg	4	4	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	20-Aug-2019	20-Aug-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 4 Domestic Shorthair (crossbred) cats (Mel, male, 8 years old, 4 kg; Mika, female, 10 years old, 3.5 kg; Nil, female, 8 years old, 3.5 kg; Miguel, male, 2 years old, 3 kg) received a fractionated dose of one pipette of FRONTLINE SPOT-ON CATS (FL) (lot and exp date are unknown, topical, btw the shoulder blades and back; off-label use) administered by the reporter on 20 Aug 2019 for flea treatment. Lack of efficacy is suspected because the cats remain with live fleas. FL has been administered once a year with no issue (1st adm date not provided). Environment not treated. No further information is available.
30-Sep-2019	UAE; 19BR004388; RJ, Brazil	Species: Feline Breed: Feline (unknown) Sex: X Sex qualifier: Unknown Age: 2.50 Year(s) Weight: 2.5 - 4.5 kg	3	3	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	21-Sep-2019	30-Sep-2019	9 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, three cats (2.5 years old to 4 years old; 2.5 kg to 4.5 kg) were treated with one vial of FRONTLINE PLUS CATS (FL) (003/18A, unknown exp date, topical, btw the shoulder blades), applied to each one by the reporter on 21 Sep 2019, for flea treatment. The animals remain with fleas. Environment treated with Butox®. FL has been applied every 4 months since date not specified. There is also a dog in this household that was treated with an unknown product and it has no issue. No further information is expected.
30-Sep-2019	UAE; 19BR004400; SP, Brazil	Species: Canine Breed: Shih Tzu Sex: F Sex qualifier: Unknown Age: 2.00 Year(s) Weight: 6.5 kg	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	Jul-2019*	Jul-2019*	0 Day(s)	D-D	Suspected lack of efficacy claim: As reported by animal owner by phone, Molly, a female Shih Tzu of 6,5Kg and 2 years old was treated with an unknown dose of FRONTLINE SPRAY (batch and exp date unknown), on the whole body, against the fur direction, by the reporter on an unknown date (Jul 2019*) for for unknown reason. The reporter says that FL did not work. A SAE for NEXGARD was reported by the customer (19BR004396). No further information is available.
30-Sep-2019	UAE; 19BR004436; -, Brazil	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier:	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON	Sep-2019*	Sep-2019*	0 Day(s)	D-D	suspected lack of efficacy claim: As reported by the owner on the social media, a cat (other signalment unknown) received FRONTLINE (unsubstantiated) administered by unknown person on unknown date for unknown reason (Sep 2019*) and after that fleas are still being seen. This is the extent of the information available

N/A signifies the information for this field is either not available or not applicable

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

Report printed on 25-Oct-2019 at 8:39:59PM

*indicates Approximate date or weight

Page 82 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00089

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Unknown Age: - Weight: Unknown				Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company					
26-Sep-2019	UAE; 19BR004499; -; Brazil	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	Sep-2019*	Sep-2019*	0 Day(s)	D-D	Suspected lack of efficacy Claim: As reported by unknown person on social media an unknown number of cats, received FRONTLINE PLUS (unsubstantiated) (batch and exp date unknown) for unknown reason on unknown date (Sep 2019*). Lack of efficacy is suspected because 'it did not worth and owner just spent money on it'. This is the extent of information available.
29-Sep-2019	UAE; 19BR004506; -; Brazil	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	3	3	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	01-Sep-2019*	01-Sep-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pets owner, an unknown number of cats received FRONTLINE (unsubstantiated) (lot, exp date, route and application site unknown), administered by the reporter on date not informed (1 Sep 2019*). Lack of efficacy is suspected. This is the extent of the information available.
28-Sep-2019	UAE; 19BR004570; RJ; Brazil	Species: Canine Breed: Medium crossbred (10 - 20 Kg) Sex: F Sex qualifier: Unknown Age: 4.00 Year(s) Weight: 15 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	01-Sep-2019*	01-Sep-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, an unknown number of female dogs, received FRONTLINE PLUS DOG M (FL) (unsubstantiated) (lot and exp date unknown), administered twice in the last month (1 Sep 2019* and 24 Sep 2019) for flea and tick treatment. The reporter says that the product wasn't effective as she still see fleas. Environment treated with unknown product. There are other dogs that were treated with FL with the same issue living in this house (see case 19BR004571). This is the extent of the information available. UPDATE 30 SEP 2019 - The pet owner informed that Mila, a female medium crossbred dog of 4 years old and 15 kg, was treated with one vial of FRONTLINE PLUS DOG M (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 1 Sep 2019* and 24 Sep 2019, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. In addition, the pet is scratching himself due to fleas. Environment treated with an unknown product. FL has been applied every 4 months since date not specified. There is another dog that was treated with FL with the same issue living in this house (see case 19BR004571). No further information is expected.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 83 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00090

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
28-Sep-2019	UAE; 19BR004571; RJ; Brazil	Species: Canine Breed: Small crossbred (<10 Kg) Sex: F Sex qualifier: Unknown Age: 3.00 Year(s) Weight: 6 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	01-Sep-2019*	01-Sep-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, an unknown number of female dogs, received FRONTLINE PLUS DOG S (FL) (unsubstantiated) (lot and exp date unknown), administered twice in the last month (1 Sep 2019* and 24 Sep 2019) for flea and tick treatment. The reporter says that the product wasn't effective as she still see fleas. Environment treated with unknown product. There are other dogs that were treated with FL with the same issue living in this house (see case 19BR004570). This is the extent of the information available. UPDATE 30 SEP 2019 - The pet owner informed that Felicia, a female small crossbred dog of 3 years old and 6 kg, was treated with one vial of FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown, topical, btw the shoulder blades), applied by the reporter on 1 Sep 2019* and 24 Sep 2019, for flea treatment. Lack of efficacy is suspected because the pet remains with fleas. In addition, the pet is scratching himself due to fleas. Environment treated with an unknown product. FL has been applied every 4 months since date not specified. There is another dog that was treated with FL with the same issue living in this house (see case 19BR004570). No further information is expected.
29-Sep-2019	UAE; 19BR004594; MA; Brazil	Species: Canine Breed: Small crossbred (<10 Kg) Sex: F Sex qualifier: Unknown Age: 2.00 Year(s) Weight: 5.8 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	31-Aug-2019*	31-Aug-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Safira, a female 2 years old, 5.8 Kg mixed breed dog, received FRONTLINE PLUS DOG S (FL) (lot and exp date are unknown), administered topically (btw the shoulder blades) according to the label, by the reporter on the end of August (31 aug 2019*) for tick treatment as the dogs were infested 15 days before the treatment. Lack of efficacy is suspected because the dog still infested with ticks, she treats the environment with unknown product weekly and the dogs have outdoor access. The infestation is reducing however still ongoing. Another SLOE reported on case 19BR004596. This is the extent of the information available.
29-Sep-2019	UAE; 19BR004596; MA; Brazil	Species: Canine Breed: Medium crossbred (10 - 20 Kg) Sex: M Sex qualifier: Unknown Age: 5.00 Year(s) Weight: 10.9 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	31-Aug-2019*	31-Aug-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, Bewouff, a male 5 years old 10.9 Kg mixed breed dog, received FRONTLINE PLUS DOG M (FL) (lot and exp date are unknown), administered topically (btw the shoulder blades) according to the label, by the reporter on the end of August (31 aug 2019*) for tick treatment as the dogs were infested 15 days before the treatment. Lack of efficacy is suspected because the dog still infested with ticks, she treats the environment with unknown product weekly and the dogs have outdoor access. The infestation is reducing however still ongoing. Another SLOE reported on case 19BR004594. This is the extent of the information available.
27-Sep-2019	UAE; 19BR004605; -, Brazil	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown	01-Sep-2019*	01-Sep-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, an unknown dog received FRONTLINE (Unsubstantiated) (FL) (batch, exp date, route and application site unknown), applied by the reporter on unknown date (1 Sep 2019*) for flea treatment. The owner believes that FL is not working because her dog continued infested by fleas. The current status of the dog is unknown. FL was used in the past with no issue (dose frequency and date of first administration are unknown). Also she says that in the past after product use it was possible to see where it was used in the fur, however now it dries and disappear quickly. No further information

N/A signifies the information for this field is either not available or not applicable

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

Report printed on 25-Oct-2019 at 8:39:59PM

*indicates Approximate date or weight

Page 84 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00091

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Was the product used ok?: Unknown to Company					is available.
27-Sep-2019	UAE; 19BR004624; -; Brazil	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	Sep-2019*	Sep-2019*	0 Day(s)	D-D	Suspected adverse event Claim: As reported by the pet owner, an unknown dog, (signalment unknown) received FRONTLINE (FL) (Unsubstantiated) (batch and exp date unknown), administered by the owner on unknown date (Sep 2019*) for unknown reason. After product use, the owner says her dog presented unknown reaction and had to be evaluated by the vet, she was bathed. Same thing happened to another dog. The dogs were treated with FL in the past with no issue. No further information is available.
19-Sep-2019	UAE; 19BR004864; SP; Brazil	Species: Feline Breed: Feline (unknown) Sex: M Sex qualifier: Unknown Age: 1.00 Year(s) Weight: 3.9 - 4.500 kg*	3	3	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	04-Sep-2019	04-Sep-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: As reported by the pet owner, 3 cats (male, from approx. 1 to 8 years, from 3.9 to 4.5 kg) received one pipette of FRONTLINE PLUS CATS (FL) (lot and exp date, topical, btw the shoulder blades) administered by the reporter on 4 Sep 2019 for flea treatment. Lack of efficacy is suspected because the pets remain with fleas. FL has been administered in the past (dose frequency and 1st adm date not provided) with no issue. Environment not treated. There are 18 other cats that received FL SPOT-ON CATS with the same issue in this house (see case 19BR004170). No further information is available.
23-Aug-2019	UAE; 19CH000051; -; Switzerland	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	19-Aug-2019	20-Aug-2019	1 Day(s)	D-D	As reported by the owner to the anti-poison center, a cat, other signalments unknown, in an unknown health condition, received FRONTLINE SPOT-ON CATS (BN and exp date unknown), 1 dose topically, on 19 AUG 2019, by owner for prophylaxis. The next day on 20 AUG 2019 the cat experienced itching. Then on 21 AUG 2019 the skin was reddish, the cats was restless, with heavy pruritus. The evolution of the event is unknown. This is the extent of information available.
28-Aug-2019	UAE; 19CH000052; -; Switzerland	Species: Feline Breed: Oriental Shorthair Sex: M Sex qualifier: Neutered Age: 2.00 Year(s) Weight: 5 kg	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	16-Aug-2019	26-Aug-2019	10 Day(s)	D-D	SUSPECTED LACK OF EFFICACY: as reported by the animal owner, a male CAT (breed Oriental Shorthair, weight 5 kg, 2 years old, health status good) was treated with the product FRONTLINE SPOT ON (batch R20109AW, expiry date unknown, 1 dose spot on, route of administration topical) on 16 AUG 2019. The animal owner had the impression that there is not a lot of effect. The flea circus is still present, as observed 10 days after the application. The owner has disinfected the whole environment, washed everything and thrown away. The cat was also dewormed. She has other 2 Oriental Shorthairs and 1 Burma-Mix Cats. No veterinarian was involved. This is the extent of information. This case was reported by the same animal owner 19CH000053 and 19CH000054.
28-Aug-2019	UAE; 19CH000053; -; Switzerland	Species: Feline Breed: Oriental	1	1	0	Product used: FIPRONIL SPOT	16-Aug-2019	26-Aug-2019	10 Day(s)	D-D	SUSPECTED LACK OF EFFICACY: as reported by the animal owner, a male CAT (breed Oriental Shorthair, weight 4 kg, 6 years

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 85 of 867

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

v1.2

ED_005739D_00014390-00092

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	-; Switzerland	Shorthair Sex: F Sex qualifier: Neutered Age: 6.00 Year(s) Weight: 4 kg				ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes					old, health status good) was treated with the product FRONTLINE SPOT ON (batch R20109AW, expiry date unknown, 1 dose spot on, route of administration topical) on 16 AUG 2019. The animal owner had the impression that there is not a lot of effect. The flear circus is still present, as observed 10 days after the application. The owner has disinfected the whole environment, washed everything and thrown away. The cat was also dewormed. She has other 2 Oriental Shorthairs and 1 Burma-Mix Cats. No veterinarian was involved. This is the extent of information. This case was reported by the same animal owner 19CH000052 and 19CH000054.
28-Aug-2019	UAE; 19CH000054; -; Switzerland	Species: Feline Breed: Burmese Sex: M Sex qualifier: Neutered Age: 13.00 Year(s) Weight: 3.5 kg	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	16-Aug-2019	26-Aug-2019	10 Day(s)	D-D	SUSPECTED LACK OF EFFICACY: as reported by the animal owner, a male CAT (breed Oriental Shorthair, weight 3.5 kg, 13 years old, health status good) was treated with the product FRONTLINE SPOT ON (batch R20109AW, expiry date DEC 2019, 1 dose spot one, route of administration topical) on 16 AUG 2019. The animal owner had the impression that there is not a lot of effect. The flear circus is still present, as observed 10 days after the application. The owner has disinfected the whole environment, washed everything and thrown away. The cat was also dewormed. She has other 2 Oriental Shorthairs and 1 Burma-Mix Cats. No veterinarian was involved. This is the extent of information. This case was reported by the same animal owner 19CH000052 and 19CH000053.
19-Aug-2019	UAE; 19CL000022; -; Chile	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: M Sex qualifier: Neutered Age: 12.00 Year(s) Weight: 5 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	14-Aug-2019	15-Aug-2019	1 Day(s)	D-D	On 19 August 2019, a pet shop owner reported an adverse event: A 12 year old domestic shorhair cat ("Copo", 5 kg, male, neutered) received 0.5 ml of FRONTLINE PLUS CATS (batch and expiry date unknown) topically in the neck administered by owner on 14 August 2019. One day after product administration the animal experienced alopecia at the application site. No tests were performed. No more information was provided and it is unknown if the cat recovered
11-Sep-2019	UAE; 19CL000027; -; Chile	Species: Canine Breed: Beagle Sex: F Sex qualifier: Unknown Age: 3.00 Year(s) Weight: 12 kg	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	26-Aug-2019	26-Aug-2019	0 Day(s)	D-D	On 11 SEP 2019 owner reported a lack of efficacy: A 3 year-old beagle ("Magdalena", 12 kg, female), a 6-month old boxer ("Azim", 13 kg, male) and a 2-month old German shepherd (name unknown, 3 kg, male) received dose according to weight (2-4 pumps/kg) of FRONTLINE SPRAY 250 mL (batch R01807A, expiry date March 2020) topically administered by owner on 26 AUG 2019. After product administration, the fleas did not die. Owner had used this product in the past in a previous dog with good results; she stated that when she used the product years ago the fleas died instantly (when the product was applied to the dog). Now, she does not see the same effect, she reapplied FRONTLINE SPRAY 250 mL a couple of times on the same day and the fleas did not die.
11-Sep-2019	UAE; 19CL000028; -; Chile	Species: Feline Breed: Domestic Longhair (Crossbreed)	1	1	0	Product used: FIPRONIL SPRAY Other products	26-Aug-2019	26-Aug-2019	0 Day(s)	D-D	On 11 SEP 2019 owner reported lack of efficacy: A 5 year-old domestic longhair feline ("Sofia", 4 kg, female), a 1-year old Siamese feline (name unknown, 4 kg, male) and a 5-month old Siamese cross feline (name unknown, 3.5 kg, male) received dose

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 86 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00093

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex: F Sex qualifier: Unknown Age: 5.00 Year(s) Weight: 4 kg				used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes					according to weight (2-4 pumps/kg) of FRONTLINE SPRAY 250 mL (batch R01807A, expiry date March 2020) topically administered by owner on 26 AUG 2019. After product administration, the fleas did not die. Owner had used this product in the past with a previous cat with good results; she stated that when she used the product years ago the fleas died instantly (when the product was applied to the cat) Now, she does not see the same effect, she reapplied FRONTLINE SPRAY 250 mL a couple of times on the same day and the fleas did not die.
03-Jul-2019	UAE; 19CZ000008; -; Czech Republic	Species: Canine Breed: Retriever Labrador Sex: M Sex qualifier: Neutered Age: 7.00 Year(s) Weight: 31 ozs	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	23-Apr-2019*	23-Jun-2019*	0 Day(s)	D-D	Suspected lack of expected efficacy: as reported by the animal owner, canine, Labrador Retriever, male, neutered, 7 years old, 31 kgs weight received Frontline Spot on L on 26 JUN 2019 (spot on, 1 pipette per one animal, entire content used, directly applied to the skin) between the shoulders, administered by owner for prevention and treatment of ticks. Previously the same product was used approx. 2 months ago. The animal was not bathed within 2 days from the application and neither got wet. 2 days after latest product application alive and attached but also big ticks fallen down were found. The dog was checked for ticks every day. Fleas were not present on the dog. The owner reported that there were lice (Mallophaga) and due to them the dog was scratching itself. The lice didn't disappear after administration of the product. MAH UPDATE 17 JUL 2019: case will be re-submitted as a follow-up case since the product was used according to the label and not off label. No other change done.
02-Jul-2019	UAE; 19DE000613; -; Germany	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	2019*	2019*	N/A	D-D	SLEE: as reported by the owner a unknown dog was treated with FRONTLINE SPOT ON H40 for years. This year the dog still had ticks. No more details.
03-Jul-2019	UAE; 19DE000614; -; Germany	Species: Canine Breed: Retriever (Golden) Sex: U Sex qualifier: Unknown Age: 2.00 Year(s) Weight: 30 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	2011*	2011*	N/A	D-D	As reported by a pharmacy consultant a pet owner mentioned, that about 8 years ago her about 2 year old Golden Retriever (30 kg body weight) was treated with FRONTLINE SPOT ON H40: 3 doses in 'labeled intervals'. A few hours after each application the dog showed vomiting and lethargy. No more details.
08-Jul-2019	UAE; 19DE000625; -; Germany	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products	2019*	2019*	0 Day(s)	D-D	As reported by a trainer for pharmacies a cat (no more details available) received FRONTLINE SPOT-ON (not further specified, FRONTLINE SPOT ON FOR CATS set as best guess; route: topical/cutaneous in the neck, no more details available) administered by the animal owner, unspecified period of time. Unknown time after receiving the product, the cat presented

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 87 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00094

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: - Weight: Unknown				Route: Topical / Cutaneous Was the product used ok?: Unknown to Company					generalized hair loss. No more details available.
09-Jul-2019	UAE; 19DE000626; -, Germany	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: 41 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	25-Jun-2019*	25-Jun-2019*	0 Day(s)	D-D	SLEE: As reported by the animal owner a dog, 41 kg body weight (no more details available) was treated with FRONTLINE SPOT-ON H 40 (route: topical/cutaneous, site of administration: Neck, batchnr.: S20518AR, exp. date: 03.2021) by the animal owner, due to flea/tick treatment. The dog received a first dose on 25 June 2019. Due to the fact that the dog still had fleas, a second dose was given on 27 June 2019. On 2 July 2019 the dog received a third dose (off-label: overdose, intervals). Finally, the dog received a fourth dose on 7 July 2019, this time the dog had no fleas anymore. According to the owner the dog was treated with FRONTLINE SPOT-ON H 40 last year with success, but this time the product had showed no efficacy against fleas until the last dose was given. The house was vacuumed, blankets washed at 60°C, hands disinfected. No more details available.
10-Jul-2019	UAE; 19DE000627; -, Germany	Species: Rabbit Breed: Rabbit (unknown) Sex: U Sex qualifier: Unknown Age: 2.00 Year(s) Weight: 2 kg	2	2	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Contraindication per label)	08-Jul-2019	08-Jul-2019	0.5 Day(s)	D-D	As reported by the animal owner 2 rabbits (2 years old each and 2 kg body weight approximately, good general condition) were treated with half a dose of FRONTLINE SPOT-ON K (route: topical/cutaneous, no more details available, off-label: contraindication species) by the animal owner on 8 July 2019, due to flea infestation. The animals licked themselves directly after application and swallowed the product accidentally. A few hours later the rabbits showed loss of appetite. The rabbits are kept in the hutch since the treatment (because a hedgehog full of fleas is around) and that could be a reason for the loss of appetite as well. No more details available.
11-Jul-2019	UAE; 19DE000635; -, Germany	Species: Feline Breed: European Sex: M Sex qualifier: Neutered Age: 6.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	2017*	2017*	N/A	D-D	As reported by the animal owner a cat, male neutered, 6 years old (no more details details available) has been treated topically with Frontline Spot on K (no more details available) administered by the animal owner for years (exact period of time: unknown), due to flea/tick treatment. The cat always gets sleepy (coded as apathy) after the application for about 1 day. The owner thinks that a hormone condition (hypersexuality) may cause this symptom but does not exclude stress as a trigger as well, because the cat is "mad" at his mistress during this time. No further details available.
11-Jul-2019	UAE; 19DE000637; -, Germany	Species: Feline Breed: European Sex: F Sex qualifier: Neutered Age: - Weight: 7.000 kg*	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the	04-Jul-2019	04-Jul-2019	0 Day(s)	D-D	SLEE and AE: As reported by the animal owner an European long haired cat, 7 to 8 kg body weight, female neutered, in good general condition (no more details available) was treated once topically in the neck with Frontline Spot-on K (1 dose, batchnr.: S21015BW, exp. date 06/2021) by the owner on 4 July 2019, due to flea/tick treatment. Despite the treatment the cat continuously had fleas. Environmental treatment: vacuuming, clothes washing at 60°C but no insecticides. Apart from that, the cat showed loss of appetite half a day after the treatment (ate treats but no wet food). No more

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 88 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00095

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						product used ok?: Yes					details available. This case was reported both SLEE and AE.
12-Jul-2019	UAE; 19DE000648; -; Germany	Species: Feline Breed: European Sex: U Sex qualifier: Unknown Age: 8.00 Year(s) Weight: 5 kg	2	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	21-Jun-2019*	22-Jun-2019*	1 Day(s)	D-D	As reported by trainer for staff of pharmacies a cat, breed European, age 8 years, 5 kg body weight, in good general condition (no more details available) was treated once topical/cutaneous with 1 dose with FRONTLINE SPOT-ON K (no more details available) administered by the animal owner on 21 June 2019 approx. due to flea/tick prophylaxis. One day after the application the cat showed hair loss in the site of administration, but no itching. No further details available. On 18 July 2019 follow up received via Email: hair/fur is growing again. Apart from that, the owner has another cat in the house who received Frontline and had no AE. No further details available.
16-Jul-2019	UAE; 19DE000654; -; Germany	Species: Canine Breed: Canine Other Sex: M Sex qualifier: - Age: 9.00 Year(s) Weight: 8.5 kg*	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: No (Treatment / vaccination program not respected)	2017	2017*	N/A	D-D	SLEE: As reported by the animal owner his Bolonka Zwetna dog (9 years old, male intact, weighing 8-9 kg) was treated topically in the neck with 1 dose of FRONTLINE SPOT-ON H 20 (batch no P21619AL - invalid, expiry date Nov 2019) by the animal owner, due to flea infestation begin of Jul 2019 twice 14 days apart (off-label: overdose, intervals). According to the owner the product showed no efficacy against fleas. Some kind of environment treatment suitable for stables was used at the time of second Frontline administration (no further details). The owner mentioned, that he used the environment spray he had left from the last flea infestation in 2017 where Frontline also showed no efficacy. No more details.
12-Jul-2019	UAE; 19DE000656; -; Germany	Species: Canine Breed: German Shepherd Dog Sex: U Sex qualifier: Unknown Age: - Weight: 30 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	Jul-2019*	Jul-2019	5 Day(s)	D-D	SLEE: As reported by the animal owner a German Shepherd dog, 30 kg body weight (no more details available) was topically/cutaneous treated with FRONTLINE SPOT-ON H 40 application in the neck (no more details available) by the animal owner, due to flea/tick treatment in July 2019 approx.(no more details available). 3-4 days after the application, the animal owner noticed less ticks and the ones that were already attached to the dog died. However, later on the dog again had ticks. No more details available.
18-Jul-2019	UAE; 19DE000657; -; Germany	Species: Feline Breed: Feline (unknown) Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	2009*	2009*	0 Day(s)	D-C	As reported by a trainer for the staff of pharmacies a male cat (further details unknown) showed 'attack of rheumatism' (MAH comment: coded as Joint pain NOS) unknown time after Frontline (not further specified) and the animal has not shown this symptom before treatment. MAH comment: Frontline Spot-On K set as best guess. This incident happen 'a long time ago'. No more details available.
18-Jul-2019	UAE; 19DE000659; -; Germany	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier:	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other	11-Jul-2019*	11-Jul-2019*	0 Day(s)	D-D	SLEE: As reported by a pharmacy an unknown cat was treated once topically with 1 dose of FRONTLINE SPOT ON K on about 11 Jul 2019 by the owner for flea treatment. 1 week later the cat was brought to a vet and showed intense flea infestation and erythema at the abdomen. Cat is known to suffer from flea allergy. The cat

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 89 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00096

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Unknown Age: - Weight: Unknown				products Route: Topical / Cutaneous Was the product used ok?: Yes					was treated with an injection of cortisone. No more details. This case was reported as SLEE.
20-Jul-2019	UAE; 19DE000664; -, Germany	Species: Feline Breed: Maine Coon Cat Sex: X Sex qualifier: Not applicable Age: 12.00 Week(s) Weight: 945 - 985 gms	2	2	1	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Contraindication per label)	12-Jul-2019*	16-Jul-2019*	4 Day(s)	D-A	As reported by the owner 2 crossbreed (Maine Coon/European) kittens, 12 weeks old, weighing 945 g and 985 g, respectively, were brought in a new household (Maine Coon cattery) without any vaccination at about 9 Jul 2019. They were treated topically in the neck with 1 dose of Frontline Combo Spot-on Cats (off-label use: kittens are too light) on about 12 Jul 2019 by the animal owner. Approx. 4 days after the treatment the male kitten showed anorexia, apathy, and vomiting. The very next day (17 Jul 2019) he also had diarrhea and was brought to a vet. There an antibiotic was administered (no more details available) and the kitten received electrolytes. The full blood analysis showed a severe leukopenia but no other findings. On 18 Jul 2019 he received antibiotic treatment again, but the general condition worsened and on 19 Jul 2019 the male kitten died. No necropsy. Since 19 Jul 2019 the female kitten also showed anorexia, increasing apathy, and vomiting, no defecation. On 24 Jul 2019 she was apathic and had diarrhea, on 25 Jul 2019 she ate by herself and the feces were firmer. The kitten was treated the last days with some penicillin p.o. (no further details) and some stool sample was send to a lab (giarida negative). Other cats from the same breeder/owner are without similar symptoms and were not treated with Frontline or Frontline Combo recently, but have received these products in the past without any problems. Additional information: the new owner also has a farm with horses and stray cats.
29-Jul-2019	UAE; 19DE000693; -, Germany	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	May-2019*	May-2019*	N/A	D-D	SLEE: As reported by the owner his dog (no further details) was treated in the last 3 month with Frontline (FRONTLINE SPOT-ON H 20 as best guess, no details about dosage, treatment interval, batch) due to flea and tick treatment. In this period he found 18 ticks on his dog and suspects a lack of efficacy .
01-Aug-2019	UAE; 19DE000701; -, Germany	Species: Feline Breed: European Sex: F Sex qualifier: Neutered Age: 16.00 Year(s) Weight: 4.32 kg	4	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: Bravecto 250 mg Lösung zum Auftropfen auf die Haut für mittelgroße Kat; Route: unknown Was the product used ok?: Unknown	2019*	2019*	N/A	D-B	Reason for treatment: Ectoparasitic prophylaxis Suspected adverse reaction: 4 cats of one household received treatment with Bravecto spot on 250 mg on 10 Jun 19 from their owner (unknown if neck or base of skull). One of these 4 cats showed apathy the next day (11 Jun 19). On 12 Jun 19 this concerned cat showed head tremor for approx 30 min and salivation. These signs repeated itself daily, the tremor episodes lasted between 10 to 60 min each. On 17 Jul 19 no such episodes occurred again and the owner assumed the cat was recovered again. On 18 Jul 19 however, signs returned worse than ever according to owner, furthermore, concerned cat showed unstable gait. Therefore, the cat was transferred to a vet clinic. There the blood values (no more details available) were examined and an x-ray was taken, both within physiological borders. The clinic

N/A signifies the information for this field is either not available or not applicable

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

Report printed on 25-Oct-2019 at 8:39:59PM

*indicates Approximate date or weight

Page 90 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00097

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						to Company					speaks of focal, epileptiform convulsions and started therapy with 20mg/kg levetiracetam for 7 weeks. How the cat reacts towards this therapy is unknown for the initially reporting vet practice. Note: Cat reacted similar after treatment with Frontline (more specific details to this are unavailable). Follow up phone conversation with animal owner on 23 Jul 19 revealed, that concerned cat is recovered, under anti-epileptic therapy no more episodes occurred (only every once in a while hypersalivation occurs but this might also due to the anti epileptic therapy). There was no neurological work up performed in the vet clinic. Owner mentioned that also mother and son of concerned cat show slight reactions after an another unknown antiparasitic treatment. According to her own vet this shows that the whole family appears to be more susceptible to some parts of unknown antiparasitic. Case closed. NCA comment: unknown Frontline added as suspect drug according to narrative. [State of health: Good]
03-Aug-2019	UAE; 19DE000715; -; Germany	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	27-Jul-2019*	Jul-2018*	N/A	D-D	SLEE: As reported by the animal owner a dog (no more details available) received FRONTLINE SPOT-ON H 10 (no more details available) by the animal owner (no specified period of time, best guess at the end the July 2019), due to flea/tick treatment. According to the animal owner Frontline Spot on H 10 showed lack of efficacy against fleas. No more information available.
09-Aug-2019	UAE; 19DE000722; -; Germany	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	3	3	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	Aug-2019*	Aug-2019*	0 Day(s)	D-D	SLEE: As reported by the animal owner 3 cats (no more details available) received FRONTLINE SPOT-ON K (product unsubstantiated, no more details available) by the animal owner in August 2019 (best guess, no specific period of time), due to flea/tick treatment. According to the animal owner Frontline Spot-on did not show any efficacy. No more details available. Dog from the same household handled in DEU-BIAHPV-19DE000723, cases are linked.
09-Aug-2019	UAE; 19DE000723; -; Germany	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	Aug-2019*	Aug-2019*	0 Day(s)	D-D	SLEE: As reported by the animal owner 1 dog (no more details available) received FRONTLINE SPOT-ON H 20 (product unsubstantiated, no more details available) by the animal owner in August 2019 (best guess, no specific period of time), due to flea/tick treatment. According to the animal owner Frontline Spot-on did not show any efficacy. No more details available. Same reporter as DEU-BIAHPV-19DE000722, cases are linked.
12-Aug-2019	UAE; 19DE000724; -; Germany	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier:	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other	Aug-2019*	Aug-2019*	0 Day(s)	D-D	SLEE: As reported by the animal owner FRONTLINE SPOT-ON K (no more details available) was administered to a cat (number approx., no more details available) by the animal owner in August 2019 (best guess, no specific period of time), due to flea/tick treatment. According to the animal owner Frontline Spot-on did not

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 91 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00098

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Unknown Age: - Weight: Unknown				products Route: unknown Was the product used ok?: Unknown to Company					show any efficacy. No more details available. Same reporter as DEU-BIAHPV-19DE000725, cases are linked.
12-Aug-2019	UAE; 19DE000725; -, Germany	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	Aug-2019*	Aug-2019*	0 Day(s)	D-D	SLEE: As reported by the animal owner FRONTLINE SPOT-ON H 20 (no more details available) was administered to a dog (number approx. no more details available) by the animal owner in August 2019 (best guess, no specific period of time), due to flea/tick treatment. According to the animal owner Frontline Spot-on did not show any efficacy. No more details available. Same reporter as DEU-BIAHPV-19DE000724, cases are linked.
12-Aug-2019	UAE; 19DE000727; -, Germany	Species: Feline Breed: European Sex: M Sex qualifier: Neutered Age: 15.00 Month(s) Weight: 4 kg	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Low dose)	07-Aug-2019*	07-Aug-2019*	immediatly	D-C	As reported by the animal owner a cat, male neutered, 15 months old, 4 kg body weight in good condition received Frontline SPOT-ON K (0.5 dose, topical/cutaneous in the neck, means low dose) by the animal owner some time last week (MAH comment: 7 Aug 2019 set as best guess), due to flea/tick treatment. The cat immediately showed rigid standing and hypersalivation. The owner excludes the possibility that the cat could have had oral contact with the product. After 2 hours everything was fine again. No more details available.
12-Aug-2019	UAE; 19DE000728; -, Germany	Species: Feline Breed: European Sex: U Sex qualifier: Unknown Age: - Weight: 4.5 kg	2	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	2017*	05-Aug-2019*	3 Day(s)	D-D	SLEE: As reported by the animal owner two European cats, 4.5 kg body weight in good condition had been treated with FRONTLINE SPOT-ON K for years, due to flea/tick treatment. The affected cat got the last FRONTLINE SPOT-ON K (topical/cutaneous application in the neck, 1 dose monthly. Batchnr.: T 20110AW, Exp. date: 12/21) 10 days ago, the other cat would have been treated a few days later (unknown if this second cat was treated at all). After the application, the animal owner went on vacation. A relative reported a few days ago that the cat is increasingly itching. After returning from vacation, the animal owner noticed flea dermatitis. The cat was brought to the attending vet who had to inject cortisone (no further details). No more details available.
18-Aug-2019	UAE; 19DE000739; -, Germany	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: 4.9 kg	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	Jul-2019*	Jul-2019*	0 Day(s)	D-D	SLEE: As reported by the animal owner a cat (4.9 kg body weight, no further details) received FRONTLINE SPOT-ON K (batchnr: S20706AW, exp. date 04/2021, 1 dose 1x month. No information on route and site of administration) by the animal owner, due to flea/tick prophylaxis on their vacation (no specific period of time, best guess July 2019), as last year there was a flea problem in their holiday accomodation. However, the cat showed flea infestation. So the animal owner used a fogger (no further details) in the holiday accomodation. Unknown time later, the cat received a second administration of FRONTLINE SPOT-ON K (1 dose). Despite these procedures, the animal owner combed out 23 fleas from the cat. No more details available.
21-Aug-2019	UAE;	Species: Avian	1	1	0	Product used:	07-Aug-2019*	21-Aug-2019*	2 Week(s)	D-C	As reported by the attending vet a male mallard (about 1 kg body

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
 Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
 *indicates Approximate date or weight

Page 92 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00099

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	19DE000753; -, Germany	Breed: Duck Sex: M Sex qualifier: - Age: - Weight: 1 kg*				FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Species not indicated / recommended)					weight, no further details) was treated topically about 2 weeks ago (MAH comment: 7 Aug 2019 set by best guess) with FRONTLINE SPRAY (off-label use: species not indicated, indication not indicated; no further details) due to myiasis of the uropygial gland. After the treatment the duck was taken care of and on 21 Aug 2019 it was brought to some water. The duck sank immediately and almost drowned. The attending vet wonders Frontline spray may have 'removed the fat of the feathers' (coded as 'Application site feather change'). On 22 Aug 2019 the vet reported that the duck seems to be 'more impregnated again'. No further information.
02-Sep-2019	UAE; 19DE000782; -, Germany	Species: Feline Breed: European Sex: M Sex qualifier: Neutered Age: 3.00 Year(s) Weight: 4 kg	2	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	27-Aug-2019	27-Aug-2019	N/A	D-C	As reported by a pharmacist who is the animal owner at the same time she treated her 2 cats with FRONTLINE SPOT-ON K (topical-cutaneous application, 1x pipette per animal in the neck, batch number S20814AW, exp. date 05/2021) on 27 August 2019, due to prophylaxis/flea + tick control. One of them, a European cat, male neutered, 3 years old, 4 kg body weight in good condition, showed reddened pinnae and scaly skin on head and ears after 2 hours. On 29 August 2019, the cat got a wound in the neck, due to scratching. The animal owner treated the cat locally with Octenisept. No more information available.
02-Sep-2019	UAE; 19DE000783; -, Germany	Species: Feline Breed: Persian (No Further Description) Sex: U Sex qualifier: Unknown Age: - Weight: 4 kg	2	2	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	12-Aug-2019*	26-Aug-2019*	0 Day(s)	D-D	SLEE: As reported by the animal owner 2 Persian cats, both 4 kg body weight in good general condition (no further details available) were treated with FRONTLINE SPOT-ON K (topical/cutaneous administration, administration site-neck, 1x pipette each, no more details available) by the animal owner 3 weeks ago (on 12 Aug 2019 approx.) due to flea/tick treatment. The cats were treated with Bravecto at the beginning of Apr 2019, due to flea/tick treatment (no more details available). The animal owner was discharged from hospital 3 weeks ago and found the cats full of fleas. Therefore, the animal owner started to treat the cats with FRONTLINE SPOT-ON, sprayed the household with BOLFO Umgebungsspray and washed their blankets. Despite this procedure, the cats still had fleas. For this reason, the animal owner treated the cats with FRONTLINE once again 1 week ago (on 26 Aug 2019 approx.). The cats are indoor cats, but there are 2 dogs in the household. Same reporter as DEU-BIAHPV1P-19DE000784, and DEU-BIAHPV1P-19DE000785, cases are linked. No more details available.
02-Sep-2019	UAE; 19DE000784; -, Germany	Species: Canine Breed: Canine Other Sex: U Sex qualifier: Unknown Age: - Weight: 8.5 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	12-Aug-2019*	26-Aug-2019*	0 Day(s)	D-D	SLEE: As reported by the animal owner a Spitz dog, 8.5 kg body weight in good general condition (no further details available) was treated with FRONTLINE SPOT-ON H 10 (topical/cutaneous administration, administration site-neck, 1x pipette, no more details available) by the animal owner 3 weeks ago (on 12 August 2019 approx.) due to flea/tick treatment. The dog was treated with Bravecto at the beginning of April 2019, due to flea/tick treatment (no more details available). The animal owner was discharged from hospital 3 weeks ago and found the dog full of fleas. Therefore, the animal owner shaved and bathed the dog and started treatment with FRONTLINE. The owner also sprayed the household with BOLFO and washed their blankets. Despite this procedure, the dog still had fleas. For this reason, the animal

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 93 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00100

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											owner treated the dog with FRONTLINE once again 1 week ago (on 26 August 2019 approx.). The dog goes regularly outside and there are 2 cats and 1 other dog in the household. Same reporter as DEU-BIAHPV1P-19DE000783 and DEU-BIAHPV1P-19DE000785, cases are linked. No more details available.
02-Sep-2019	UAE; 19DE000785; -; Germany	Species: Canine Breed: Dachshund Sex: U Sex qualifier: Unknown Age: - Weight: 6 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	12-Aug-2019*	26-Aug-2019*	0 Day(s)	D-D	SLEE: As reported by the animal owner a dog, Dachshund, 6 kg body weight in good general condition (no further details available) was treated with FRONTLINE SPOT-ON H 10 (topical/cutaneous administration, administration site=neck, 1x pipette, no more details available) by the animal owner 3 weeks ago (on 12 August 2019 approx.) due to flea/tick treatment. The dog was treated with Bravecto at the beginning of April 2019, due to flea/tick treatment (no more details available). The animal owner was discharged from hospital 3 weeks ago and found the dog full of fleas. Therefore, the animal owner shaved and bathed the dog and started treatment with FRONTLINE. The owner also sprayed the household with BOLFO and washed their blankets. Despite this procedure, the dog still had fleas. For this reason, the animal owner treated the dog with FRONTLINE once again 1 week ago (on 26 August 2019 approx.). The dog goes regularly outside and there are 2 cats and 1 other dog in the household. Same reporter as DEU-BIAHPV1P-19DE000783 and DEU-BIAHPV1P-19DE000784, cases are linked. No more details available.
06-Sep-2019	UAE; 19DE000791; -; Germany	Species: Canine Breed: Retriever (Golden) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	Sep-2019*	Aug-2019*	N/A	D-D	As reported by the animal owner a Golden Retriever dog (no further details) was treated with FRONTLINE (MAH comment: Frontline Spot-on H 40 set as best guess) in Aug 2019 (set as best guess). Unknown time after the treatment the dog showed pruritus. No further details.
16-Sep-2019	UAE; 19DE000803; -; Germany	Species: Canine Breed: Canine Other Sex: F Sex qualifier: Unknown Age: 7.50 Year(s) Weight: 5.5 kg	1	1	0	Product used: FIPRONIL SPRAY Other products used: CAPSTAR 11.4mg; Route: unknown Was the product used ok?: Unknown to Company	N/A	27-Sep-2016	N/A	D-D	Chihuahua, 4,5 Kg, female, 6,5 years and Zwergratonero Mallorquin, 5,5 kg, female, 7,5 years received Frontline against their fleas, no success. Then both dogs received Capstar (bought via internet) 4 times with 48 h between the applications, fleas still visible, dog of her daughter has also fleas, owner suspects lack of efficacy
16-Sep-2019	UAE; 19DE000804; -; Germany	Species: Canine Breed: Chihuahua Sex: F Sex qualifier: Unknown Age: 6.50 Year(s)	1	1	0	Product used: FIPRONIL SPRAY Other products used: unspecified	N/A	27-Sep-2016	N/A	D-D	Chihuahua, 4,5 Kg, female, 6,5 years and Zwergratonero Mallorquin, 5,5 kg, female, 7,5 years received Frontline against their fleas, no success. Then both dogs received Capstar (bought via internet) 4 times with 48 h between the applications, fleas still visible, dog of her daughter has also fleas, owner suspects lack of efficacy.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 94 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00101

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: 4.5 kg				product; Route: unknown Was the product used ok?: Unknown to Company					
11-Sep-2019	UAE; 19DE000807; -; Germany	Species: Feline Breed: Feline (unknown) Sex: M Sex qualifier: Unknown Age: 6.00 Month(s) Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	Sep-2019*	Sep-2019*	N/A	D-D	As reported by the animal owner a male cat, 6 months old approx. (no more details available) was treated with FRONTLINE SPOT-ON K (product unsubstantiated, no more details available) by the animal owner, due to unknown condition (no specified period of time, best guess September 2019). Unknown time later the cat shows 'disturbing signs like gagging, screams wildly, and runs through the entire apartment'. No more details available.
15-Sep-2019	UAE; 19DE000813; -; Germany	Species: Feline Breed: European Sex: U Sex qualifier: Unknown Age: 9.00 Year(s) Weight: 5 - 6 kg	3	3	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Species not indicated / recommended)	17-Jul-2019	15-Sep-2019*	4 Week(s)	D-D	SLEE: As reported by the animal owner 3 European cats (living in the same household, between 9 to 15 years old, between 5 to 6 kg body weight in good general condition) received Frontline Spot-on H 10 (1 dose topically in the neck, batch number: S20316AL: exp. date, 02/2021; off-label use: species not indicated) on 17 Jun 2019 and on 18 August 2019, due to flea/tick treatment. The animal owner has now discovered more fleas on the cat than before starting with the therapy. The animal owner treated the apartment with a fogger (no further details) and a spray (no further details). All 3 cats get regularly outside with access to littered courtyard in the neighborhood. No more information available.
10-Sep-2019	UAE; 19DE000822; -; Germany	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: 37 - 45 kg	2	2	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	31-Aug-2019*	10-Sep-2019	10 Day(s)	D-D	SLEE: As reported by the animal owner, 2 large dogs, 1x 37 kg bodyweight and 1x 45 kg bodyweight were treated with Frontline Spot-on H 40 (product unsubstantiated, the heavier dog received at least 1.5 pipette of the product, the other dog 'the rest', no more details available) by the animal owner on approx. 31 Aug 2019 due to flea/tick treatment. According to the animal owner, both dogs still are full of fleas. No more details available.
08-Sep-2019	UAE; 19DE000823; -; Germany	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: 12.00 Week(s) Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	Aug-2019*	Sep-2019*	0 Day(s)	D-D	SLEE: As reported by the animal owner a dog (12 weeks old, no further details) was treated twice with FRONTLINE SPOT-ON H 20 (no further details). The owner still noticed fleas after 1 week. No further information available.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 95 of 867

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

v1.2

ED_005739D_00014390-00102

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
25-Sep-2019	UAE; 19DE000827; -, Germany	Species: Feline Breed: Feline (unknown) Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	Sep-2019*	Sep-2019*	0 Day(s)	D-D	As reported by the animal owner the coat of a red male cat turned black at the application site unknown time after using Frontline Spot On for cats. No more details.
30-Sep-2019	UAE; 19DE000831; -, Germany	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	27-Sep-2019	30-Sep-2019*	3 Day(s)	D-D	SLEE: As reported by the animal owner a dog (no further details) was treated with FRONTLINE SPOT-ON (FRONTLINE SPOT-ON H 10 set as best guess, product unsubstantiated, no further details) on 27 Sep 2019. There are still fleas visible. According to the owner they also used some fogger (no further details) in order to treat the environment. No further information. Same reporter and owner as DE-BIAHPV-19DE000832, cases are linked.
30-Sep-2019	UAE; 19DE000832; -, Germany	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	27-Sep-2019	30-Sep-2019*	3 Day(s)	D-D	SLEE: As reported by the animal owner a cat (no further details) was treated with FRONTLINE SPOT-ON (FRONTLINE SPOT-ON K set as best guess, product unsubstantiated, no further details) on 27 Sep 2019. There are still fleas visible. According to the owner they also used some fogger (no further details) in order to treat the environment. No further information. Same reporter and owner as DE-BIAHPV-19DE000831, cases are linked.
16-Sep-2019	UAE; 19DE000833; -, Germany	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	10-Sep-2019*	16-Sep-2019*	N/A	D-D	SLEE: As reported by the owner her dogs (no further details) were treated with FRONTLINE (FRONTLINE SPOT-ON H 10 set as best guess, product unsubstantiated, no further details). Owner could not see any efficacy (not further specified, SLEE for fleas and ticks set as worst case). No further information. Same reporter and owner as DE-BIAHPV-19DE000834, cases are linked.
16-Sep-2019	UAE; 19DE000834; -, Germany	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used	10-Sep-2019*	16-Sep-2019*	N/A	D-D	SLEE: As reported by the owner her cats (no further details) were treated with FRONTLINE (FRONTLINE SPOT-ON K set as best guess, product unsubstantiated, no further details). Owner could not see any efficacy (problem not further specified, so SLEE for fleas and ticks set as worst case). No further information. Same reporter and owner as DE-BIAHPV-19DE000833, cases are linked.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 96 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00103

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						ok?: Unknown to Company					
19-Jul-2019	UAE; 19DK000066; -; Denmark	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: 7 - 8 kg*	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	Jun-2019*	Jul-2019*	0 Day(s)	D-D	As reported by a pharmacist, a dog (approx. 7-8 kg bw, unknown breed, gender and age) received FRONTLINE COMBO SPOT-ON for dogs 2-10 kg (size S) LOT unknown, administered by the owner during the summer 2019 (approx JUN 2019). Two administrations were given, 4 weeks apart, for treatment against fleas. After product administration (approx JUL 2019) the owner returned to the pharmacy and complained about lack of efficacy after the second administration (not further specified).
28-Aug-2019	UAE; 19DK000078; -; Denmark	Species: Canine Breed: Retriever Labrador Sex: F Sex qualifier: Unknown Age: 1.00 Year(s) Weight: 28 - 29 kg	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Others)	2019*	Jun-2019	0 Day(s)	D-D	As reported by the animal owner, two dogs, labradors, intact females, one 1 year old, 28 kg and one 10 year old 29 kg, received FRONTLINE COMBO VET 20-40 kg, size L (LOT unknown) administered between the shoulder blades and back in dry fur close to the skin (off-label: the content should be applied on one single spot), by the owner 4 times a year, as tick and flea prevention. A dose was given in the spring 2019 and a new dose in JUN 2019. The owner reported that fleas were found on the dogs after the dose given in in spring 2019, and the treatment in JUN-2019 had no effect either. Unknown tablets were given as alternative treatment.
28-Aug-2019	UAE; 19DK000079; -; Denmark	Species: Canine Breed: Cockapoo Sex: F Sex qualifier: Unknown Age: 4.00 Year(s) Weight: 9.6 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	Mar-2019*	Jun-2019*	N/A	D-C	As reported by the animal owner, a dog, Cockerpoo, female, 4 years old, 9.6 kg (born Jun-2015), received FRONTLINE COMBO VET for 2-10 kg, size S (LOT unknown) administered topically in the neck area according to the leaflet every four weeks, throughout the spring 2019 (dates not specified), by the owner. In the middle or end of JUN 2019 (date not specified), the owner noticed that the dog was scratching a lot and was very restless and was licking itself frantically on the chest and legs. When the owner had the dog trimmed, a wound on the chest by the left leg became visible, as well as reddening of the skin and small wounds on the inner side of the legs and the backside of the right leg. The dog was brought to a vet who said that the wound on the chest was from a tick bite, and NEXGARD was prescribed as alternative treatment. The owner reported that she had not seen any ticks. The owner reported that live fleas were seen in the fur. Fleas were not present in the house and no family. The owner reported that fleas had not been detected on the dog before, except for a few ones when the dog was a puppy. The dog had been treated with Prac-Tic since it was old enough to receive treatment and the owner switched to FRONTLINE COMBO because Prac-Tic was not available. The owner reported never having problems with ticks or fleas while the dog received Prac-tic.
13-Sep-2019	UAE; 19DK000084; -; Denmark	Species: Canine Breed: Chihuahua Sex: F Sex qualifier:	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE	05-Jun-2019*	Aug-2019*	N/A	D-B	As reported by the animal owner, a dog, 'Candy', female, intact, 9 years old, 2 kg, received FRONTLINE COMBO VET SPOT-ON FOR DOGS 2-10 KG (LOT unknown) 1 dose topically applied on the 5th every month, administered by the animal owner for the past

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 97 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00104

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Unknown Age: 9.00 Year(s) Weight: 2 kg				9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company					four months, from 05 JUN 2019 to 05 SEP 2019. The dog had prior to treatment (the past year) suffered from sporadic, minor epileptic seizures, which started after treatment with an unknown chewable tablet for flea and tick prevention. During treatment with FRONTLINE COMBO VET the sporadic seizures continued. After the last two product administrations, on 05 AUG and 05 SEP 2019, the seizures appeared 12 to 24 hours after product administration. On the last administration date, 05 SEP 2019, the dog had two seizures, the first appearing 12 hours after administration and the second 24 hours after the first seizure. The dog was in heat at the time of the last two administrations. The owner was advised to discontinue the treatment in SEP 2019. Update by MAH 30-SEP-2019: added VeDDRA-code 'increased seizure frequency'.
20-Sep-2019	UAE; 19DK000086; Mørkøv; Denmark	Species: Canine Breed: Chihuahua Sex: X Sex qualifier: Unknown Age: 10.00 Year(s) Weight: 3.000 - 6.4 kg*	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Others)	08-Aug-2019	Aug-2019*	3 Week(s)	D-D	As reported by the animal owner, two dogs, chihuahua, (one female, 3.0 kg, age unknown and one 10-year old male, 6.4 kg) received FRONTLINE COMBO VET 2-10 KG (S), (LOT R62425BL, EXP OCT 2020, valid) topically applied to the neck area and rubbed in (off-label use: the content should be applied directly on one spot on the skin but not be rubbed in), administered by the owner from 08 AUG 2019 to 10 AUG 2019 for treatment against fleas (MAH comment: it is unknown if the dogs were treated more than once between AUG 8-10). The dogs had fleas at the time of treatment. After product administration (time not specified) the owner reported that the dogs were still scratching. The owner went to the vet 14 days after treatment with FRONTLINE COMBO to get another product for flea treatment. An unknown alternative product was then administered. There was also a cat (outdoor and indoor) in the household, it is unknown if the cat was treated. The dogs had previously (not further specified) been treated with FRONTLINE.
11-Jul-2019	UAE; 19ES000509; -, Spain	Species: Feline Breed: European Sex: F Sex qualifier: Lactating Age: 9.00 Week(s) Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: PUREVAX RCP FELV; Milpro small cats; Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	26-Jun-2019	07-Jul-2019	11 Day(s)	D-C	Suspected Adverse Event: As reported by the attending veterinary, Aria, an European, female cat (weight unknown) born on 01MAY2019, received 1 dose of Purevax RCP-FeLV (batch L460207 and expiry date unknown) administrated subcutaneous via by the attending veterinary on 04JUL2019. On 07JUL2019, the animal started to experience discomfort. On 08JUL2019 the animal experienced apathy, hyperthermia (40°C), trembling, lameness and articular inflammation and pain located in the carpus and elbows. The animal was treated with Metacam, but she did not improve. On 09JUL2019 the vet administrated her corticoids IM route. On 10JUL2019 the animal was totally recovered, therefore the vet decided to continue the treatment using oral corticoids. An analysis was performed and the results received on 18JUL19 showed Low hematocrit=23.2% (non regenerative anaemia), lymphopenia (256), and leukaemia and immunodeficiency both negative. Clinical history: the animal was adopted on 07JUN2019. On 04JUL2019 a FeLV-FIV test was performed with negative results. On 26JUN2019, the animal received an antiparasitic treatment Frontline Combo for cats due to she had some ticks and on 08JUN2019 the animal also received 1 tablet of Milpro for small cats. UPDATE 24JUL2019: the animal had been checked and she was fine. On 05AUG2019 the attending vet informed that the cat had been vaccinated with Purevax RCP (previous antihistamine injection) one week ago and on 09AUG2019 Aria had not experienced any adverse reaction.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 98 of 867

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00105

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
15-Jul-2019	UAE; 19ES000518; Barcelona; Spain	Species: Canine Breed: Chihuahua Sex: F Sex qualifier: Unknown Age: 5.00 Year(s) Weight: 2.9 kg*	2	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	12-Jul-2019	13-Jul-2019	1 Day(s)	D-C	Suspected Adverse Event: As reported by the animal owner, a 5 years old, 2.9 kg, Chihuahua, female dog received 1 pipette of Frontline Combo Spot On dog 2-10 kg (batch and expiry date unknown) administrated topically by the animal owner on 12JUL2019 at night. On 13JUL2019 the animal experienced vomiting, reddening of the skin, scratching and inflammation of the face and neck. When she scratched herself, she began to experience bleeding wounds. The owner took her to the veterinary center and was treated with antibiotic, antiinflammatory and antiemetic. The animal recovered. It was the first time the patient received this product and they did not know if it was possible she had licked the application zone. She usually received pipettes from another brand. The animal lives with another dog that also received the product the same day, but it did not experience any adverse event.
23-Sep-2019	UAE; 19ES000666; Asturias; Spain	Species: Feline Breed: European Sex: M Sex qualifier: - Age: 2.50 Month(s) Weight: 1 kg	1	1	0	Product used: FIPRONIL SPRAY Other products used: FIPRONIL 8.3% / S-METHOPRENE 10% / PRAZQUANTE L 8.3% / EPRINOMECTIN 0.4% SPOT ON; Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	03-Sep-2019*	13-Sep-2019	10 Day(s)	D-B	Suspected Adverse Event: As reported by pet owner, Caramelo a between 2 and a half and 3 months old, 1 kg, European male cat received 1 pipette of Broadline solution Spot on for cats <2.5 kg (batch and expiry date unknown) administrated topically between the scapula by the attending vet on 13SEP2019. When the animal was going home started to experience seizures and spasms. On 21SEP2019 the owner took the animal to the veterinary center because he had worsened. The animal was isolated. However, he experienced about two or four seizures in one hour and especially when he was falling sleep. The vet established a treatment with doxycycline (just in case the animal had a toxoplasma or Haemobartonella infection), keppra and stesolid. A blood test was performed with normal results. Also a FeLV/FIV test was performed and showed negative results. The owner and the vet dismissed the possibility that the animal had licked the product. The vet visited the animal again due to he had worsened. He was blind (not show menace reflex) and was not able to stand. He woke up startled and then convulsions evolved. On 24SEP2019 the patient had been eating correctly and only experienced a few seizure (usually when the animal was relaxed) since he had started the keppra treatment. On 25SEP2019 the animal had worsened. Vet decided to start a phenobarbital treatment and hours later the animal had improved. On 27SEP2019 Caramelo was sent home. The seizures had been controlled, however, he was still experiencing facial muscle spasms. He was being treated with phenobarbital, keppra and stesolid. On 30SEP2019 the animal had improved, but he was still experiencing blindness and trembling when he walked. Vets kept the same treatment. An analysis was performed and showed anaemia and low monocytosis, high levels of alkaline phosphatase, and leukemia and immunodeficiency both negative. On 03OCT19, Caramelo got worst. He suffered mouth spasms and twitching. An analysis was performed and all the results
18-Jul-2019	UAE; 19FI000027; -, Finland	Species: Canine Breed: Canine Other Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	2	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown	21-Jun-2019	23-Jun-2019	2 Day(s)	D-C	As reported by the animal owner, two dogs were treated, one reacted: a dog, kleinspitz, male (age and weight unknown), received FRONTLINE COMP 0.67 ml (size S) (batch unknown and route unknown) 1 dose administered by the animal owner on 21 JUN 2019. 2 days after product administration (23 JUN 2019) the dog experienced skin irritation in the neck area where the skin partly opened and a wound appeared. The dog was taken to the vet and antibiotic treatment was given PO for 10 days according to advice from att vet (not further specified). Skin lesion healed partly during the treatment, but after the end of treatment (approx. 03

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 99 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00106

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Was the product used ok?: Unknown to Company					JUL 2019) the skin lesion worsened and the wound opened again. Owner consulted at vet again on 15 JUL 2019 where the dog was sedated and the skin was cleaned. Antiseptic shampoo was used for cleaning (not further specified). On the same day (15 JUL 2019) the dog got a fever and treatment with amoxicillin-clavulanic acid 125 mg BID and robenacoxib 6 mg BID PO was started. At the time of reporting the treatment was still ongoing. The dog was still slightly lethargic and ate and drank less than normally. The dog has previously been treated with FRONTLINE (not specified) 2 years ago (2017) where a skin reaction occurred which was treated with antibiotics. MAH comment: review of case 15-AUG, case assessment changed to serious.
18-Jul-2019	UAE; 19FI000028; -, Finland	Species: Canine Breed: Pinscher (Miniature) Sex: X Sex qualifier: Neutered Age: 7.00 Year(s) Weight: 5 kg*	2	2	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	13-Jul-2019	18-Jul-2019*	5 Day(s)	D-D	As reported by an animal owner, two dogs, miniature pinschers (7 and 15 years, approx 5 kg each, one male, one female, both neutered, at good health) received FRONTLINE VET 0.67 ML (size S) (LOT S21807AX, EXP 30 NOV 2021, valid) topically administered by the owner on 13 JUL 2019. 5 days after product administration (on 18 JUL 2019) the owner found one alive tick on one of the dogs. On 19 JUL 2019 a dead tick was found and one of the dogs showed unwillingness to move (not specified which dog). The dog had recovered the next day, on 20 JUL 2019. MAH comment: This case is classified as both 'SLEE' and 'Adverse reaction', but due to a limitation of the database it might be that only the highest hierarchical product problem type, which is 'Adverse reaction', has been transmitted.
19-Jul-2019	UAE; 19FI000029; -, Finland	Species: Canine Breed: Canine (unknown) Sex: M Sex qualifier: Neutered Age: - Weight: 40 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Indication not indicated / recommended)	04-Jun-2010	07-Jun-2019	3 Day(s)	D-C	As reported by the animal owner, an 8-year old male neutered dog (breed unknown, body weight approx. 40 kg) received FRONTLINE COMP 4.02 ML (size XL) (LOT R60710, EXP FEB 2020, valid) topically applied according to the label by the animal owner on 4-JUN-2019 as tick repellent (off-label: indication). On the 7-JUN the dog experienced a painful, purulent and abscessed skin infection (MAH Veddra-coded application site pyoderma) on the site of application. The product normally left the hair wet in the neck and at the beginning the owner did not realize that it was a question of purulent skin, because the dog had very thick fur. The affected skin area was small at first, but quickly spread along the dog's neck towards the top of the head. The skin area was sore. The dog was brought to the vet and the reaction was treated by cleaning the affected area using antiseptic ointment on the lesion. The dog had previously been treated with the product without reaction. No concomitant treatment was given and the dog had no prior disease. The dog had not been bathed or gone swimming during the treatment. A collar was not used normally. The general condition of the dog had been good, though at the same time it was tame compared to normal, because the area was painful, and it strolled around restlessly. The condition improved in less than two weeks completely and no other symptoms were seen. The inflammation dried out with a gel containing antibiotics and cortisone. There was no need for oral antibiotics. On the 29- JUL the dog had completely recovered. MAH comment: the case was initially assessed non-serious, but at review of the case the assessment has been changed to serious due to the severity of the reaction.
30-Jul-2019	UAE; 19FI000034; -, Finland	Species: Canine Breed: Shetland Sheep Dog	1	1	0	Product used: FIPRONIL 10%/S	Apr-2019	May-2019*	N/A	D-D	As reported by an animal owner, a 6-year old male intact Shetland Sheepdog, body weight 15 kg, healthy, received FRONTLINE COMP VET SPOT-ON (product unsubstantiated, MAH estimated

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 100 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).
Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.
Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00107

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		(Sheltie) Sex: M Sex qualifier: - Age: 6.00 Year(s) Weight: 15 kg				METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company					size M for dogs bw 10-20 kg), 3 doses at 1 month interval administered by the owner starting APR-2019. Recently (date not specified, reported in JUL-2019) the skin of the dog started to scale off, especially on posterior areas and there was a lot of hair loss. The owner switched to Bayvantic and the symptoms were less severe. The owner also stated that in MAY the dog had ticks on skin and hair after visiting tick areas. The owner has used Frontline comp for a couple of summers. MAH comment: This case is classified as both 'SLEE' and 'Adverse reaction', but due to a limitation of the database it might be that only the highest hierarchical product problem type, which is 'Adverse reaction', has been transmitted.
20-Aug-2019	UAE; 19FI000037; -, Finland	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: 12.00 Year(s) Weight: 4.2 - 9.2 kg	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	2019*	Aug-2019*	N/A	D-D	As reported by the att vet, 2 dogs with different owners (one 12 years, 4.2 kg and one 15 years, 9.2 kg, breed and gender unknown, at good health) received FRONTLINE COMP 67/60.3 MG (size S) (LOT unknown, route and dose unknown) administered by the animal owners on an unknown date and unknown frequency. During AUG 2019 the dogs visited the clinic and the owners reported that several ticks had been found on the dogs and that these had been attached for a longer period of time. A couple of the ticks were found during the clinic visit. The dogs had not been swimming and were not washed after application.
03-Sep-2019	UAE; 19FI000039; -, Finland	Species: Feline Breed: Feline (unknown) Sex: M Sex qualifier: Neutered Age: 8.00 Year(s) Weight: 4.5 kg	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	02-Sep-2019	02-Sep-2019	0 Day(s)	D-B	As reported by att. vet, an 8-year old male neutered cat (breed unknown, 4.5 kg, of good health) received FRONTLINE VET 100 MG/ML SPOT-ON (batch R21611BX, exp. SEP-2020) unknown dose applied topically by the owner on 2-SEP-2019 around noon. At 10 pm the cat started to tremble, it was sensitive to touch, had ataxia in the hind legs and appeared to be nauseous. The trembling continued for several hours and at 2 in the night it had convulsions lying on one side attempting to get up. This lasted for half a minute. At 2.30 at the vet, cat was still trembling, pupillary reflex delayed but had no other neurological signs. In the morning the cat was normal but had itch on the site of application. The cat had not received any other medication but dogs of the family have received Bayvantic and they use a preparation containing permethrin in henhouse in the yard.
12-Sep-2019	UAE; 19FI000040; -, Finland	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: 21 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	2019*	2019*	N/A	D-D	As reported by the animal owner, a dog, 21 kg (breed, age and state of health unknown) received FRONTLINE VET 100 MG/ML SPOT-ON (LOT S21802AX, EXP NOV 2021, valid) administered by the animal owner at unknown date (MAH added 2019) and frequency, for prevention against ticks. The animal owner reported to have found approx. 20 ticks on the dog, however the time of onset was not specified. The dog had not been washed with shampoo. The dog had previously been treated with the product (date unknown) with good effect.
04-Jul-2019	UAE; 19FR000809; -, France	Species: Feline Breed: Feline crossbred Sex: X	2	2	2	Product used: FIPRONIL SPOT ON CAT Other products	22-Jun-2019	23-Jun-2019	1 Day(s)	D-A	FR-ANMV-19 CPVL 00874: T0: two cats were applied with FRONTLINE SPOT ON CHAT. T+6h: they successively displayed drunken gait, ataxia, falling, then apathy. T+9h: the first cat was presented to emergency clinic (vet college). T+11h: the second cat

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
 Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
 *indicates Approximate date or weight

Page 101 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).
 Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.
 Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00108

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: Not applicable Age: 10.00 Year(s) Weight: 3-4 kg				used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Expired)					was also examined at same emergency clinic. They were in polypnoea, and diagnosed with acute renal failure. The cats were washed and administered with fluids therapy, antiemetic, manitol, anticonvulsant, intralipids. Without improvement, both were euthanased. No necropsy performed. Note: product administered was 2 months outdated/expired. Duration of reaction: < or = 24 hours Duration of reaction (precision): approx.15 hours. Reason for treatment: Preventive. Treatment of SAR: fluids therapy, antiemetic, manitol, anticonvulsant, intralipids, washing. Outcome of SAR: Unfavorable
08-Jul-2019	UAE; 19FR000812; -, France	Species: Feline Breed: European Sex: U Sex qualifier: Unknown Age: 11.00 Year(s) Weight: Unknown	2	2	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	22-Jun-2019	23-Jun-2019	1 Day(s)	D-C	FR-ANMV-19 CPVL 00860: D0 late early night (10:00 PM), two elderly European cats are applied each with FRONTLINE SPOT ON CHAT. D1 morning (or in late night), both display ataxia, with associated lethargy and vomiting. Duration of reaction: < or = 6 hours. Duration of reaction (precision): ongoing (a few hours). Reason for treatment: fleas. Treatment of SAR: ? Investigations: ? Outcome of SAR: Unknown. FRONTLINE SPOT ON CHAT () : 1 pipette per cat; duration: once; onset time: < 6-12 hours.
11-Jul-2019	UAE; 19FR000829; -, France	Species: Feline Breed: Feline (unknown) Sex: M Sex qualifier: - Age: 8.00 Year(s) Weight: 6 kg	2	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	06-Jun-2019	07-Jun-2019	1 Day(s)	D-C	FR-ANMV-19 ANMV 01224: Case reported by the owner: 2 cats were treated with 1 pipette each of FRONTLINE COMBO SPOT-ON CHAT on 06-Jun-2019 (monthly treatment). The owner suspects that the male cat licked the female cat and ingested an amount of the product. Quickly after the product application (exact time unknown but less than 24h), the male cat began to vomit, drank frequently and stayed lying. Since then, it is sleeping a lot and its breathing presented episodes of sudden tachypnea. On 08-Jun-2019, the case was still ongoing. No vet examination available and no treatment implemented. Reason for treatment: Preventive. FRONTLINE COMBO SPOT-ON CHAT () : 1 pipette/cat, application between shoulders.
11-Jul-2019	UAE; 19FR000834; -, France	Species: Canine Breed: Border Collie Sex: U Sex qualifier: Unknown Age: - Weight: 18 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: PO-Oral Was the product used ok?: No (Route not indicated / recommended)	18-Jun-2019	18-Jun-2019	0 Day(s)	D-D	FR-ANMV-19 CPVL 00843: A Border Collie dog licked a FRONTLINE SPOT ON CHIEN M applied on another dog. It displayed nausea. Exact timing not specified: phone call before vet examination. Duration of reaction: < or = 1 hour. Duration of reaction (precision): Ongoing (< 1h). Reason for treatment: accidental ingestion. Outcome of SAR: Unknown. FRONTLINE SPOT ON CHIEN M () : < 1 spot on; duration: Once; onset time: < A few hours.
15-Jul-2019	UAE; 19FR000841; -, France	Species: Feline Breed: Chartreux Sex: M Sex qualifier: Neutered Age: 16.00 Year(s)	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products	06-Jul-2019	07-Jul-2019	1 Day(s)	D-C	FR-ANMV-19 CPVL 00938: D0: Chartreuse cat applied with FRONTLINE COMBO SPOT-ON CHAT. D1: also administrated with 1/2 tablet of COMFORTIS 270 MG COMPRIMES A CROQUER POUR CHIENS ET CHATS. Around 1 hour later, it displayed tachypnoea, associated with intense haircoat licking and agitation. Duration of reaction: < or = 1 hour. Duration of reaction

N/A signifies the information for this field is either not available or not applicable

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

Report printed on 25-Oct-2019 at 8:39:59PM

*indicates Approximate date or weight

Page 102 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00109

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: 6 kg				used: COMFORTIS 270 MG COMPRIMES A CROQUER POUR CHIENS ET CHATS; Route: Topical / Cutaneous Was the product used ok?: Unknown to Company					(precision): ongoing (35 minutes). Reason for treatment: ectoparasites. Treatment of SAR: not yet. Investigations: ? Outcome of SAR: Unknown. FRONTLINE COMBO SPOT-ON CHAT () : 1 pipette; duration: once; onset time: < 24 hours COMFORTIS 270 MG COMPRIMES A CROQUER POUR CHIENS ET CHATS () : 1/2 tablet; duration: once; onset time: 1 hour.
08-Jul-2019	UAE; 19FR000845; -, France	Species: Feline Breed: European Sex: M Sex qualifier: Neutered Age: 17.00 Day(s) Weight: 3.37 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	04-Jul-2019	04-Jul-2019	0 Day(s)	D-C	ADVERSE REACTION case: As reported by the attending vet, a neutered male European cat born on 17 JUN 2019, weighing 3.37 kg, in good condition, had received topically FRONTLINE COMBO SPOT ON CHAT (on the neck near the cat's necklace, BN: S41403AW and exp. date: OCT 2021) administered by the owner on 04 JUL 2019. Right after the product administration the cat experienced hypersalivation, significant vomiting, diarrhea and dysphagia. On 06 JUL 2019, i.e. 2 days after product administration, the cat was taken to the vet because the clinical signs were ongoing. The cat was treated with a subcutaneous fluid therapy and Prevomax and Estocelan injections. On 09 JUL 2019, the cat recovered. Note: the vet suspected that the necklace was soaked with the product and the cat must have been able to lick it many times.
05-Jul-2019	UAE; 19FR000849; -, France	Species: Canine Breed: Belgian Malinois Sex: M Sex qualifier: Unknown Age: 2.50 Year(s) Weight: 42 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	29-Jun-2019	01-Jul-2019	2 Day(s)	D-D	Suspected Adverse Event: As reported by the animal's owner, a 2.5-year-old male Belgian Malinois, 42 kg, in good condition, received one pipette of FRONTLINE COMBO SPOT-ON CHIEN XL (BN: S62505AX, Exp. date: AUG 2021) administered topically by the owner on 29 JUN 2019 for flea treatment. 2 days after product administration, on 01 JUL 2019, the animal experienced abnormal behaviour compared to usual: intense scratching on the back close to the base of the tail and overreaction without any apparent reason (encoded as "Hyperaesthesia" into Veddra). The case was ongoing at the time of this report. Note: the animal was already a little bit tired before product administration because it had been scratching itself a lot as a consequence of flea infestation.
08-Jul-2019	UAE; 19FR000851; -, France	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	Jul-2019*	Jul-2019*	4 Week(s)	D-D	Suspected Lack of Efficacy: As reported by the animal's owner, dogs (unknown signalment and exact number (2 was chosen by default)) received one pipette of FRONTLINE COMBO SPOT-ON CHIEN (product unsubstantiated) (BN and exp. date: unknown) administered topically in the neck by the owner on an unknown date (JUL 2019 was chosen by default) for flea treatment. After product administration (unknown time to onset), fleas did not disappear from the animal (efficacy described as close to zero by the owner). The owner administered a competitor product (unspecified) that was effective.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 103 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00110

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
09-Jul-2019	UAE; 19FR000854; -; France	Species: Feline Breed: European Sex: M Sex qualifier: Unknown Age: 10.00 Year(s) Weight: 4 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: FIPRONIL SPRAY; Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	26-Jun-2019	26-Jun-2019	Immediate	D-D	Suspected Lack of Efficacy: As reported by the animal's owner, a 10-year-old male European cat, 4 kg, in good condition, received one pipette of FRONTLINE COMBO SPOT-ON CHAT (BN: S41513CW, Exp. date: NOV 2021) administered topically at the base of the neck between the shoulders by the owner and FRONTLINE SPRAY (BN: S02701A; Exp. date: OCT 2021) administered topically by the owner on 26 JUN 2019 for flea treatment (the cat was infested by fleas). Since administration of both products, fleas had been still visible on the animal. The case was ongoing at the time of this report. Note: the animal had been kept indoors after administration of the products and the environment had been treated with foggers (unspecified).
10-Jul-2019	UAE; 19FR000856; -; France	Species: Feline Breed: Maine Coon Cat Sex: M Sex qualifier: Unknown Age: 14.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Low dose)	04-Jul-2019	04-Jul-2019	0 Day(s)	D-B	Suspected Adverse Event: As reported by the animal's owner, a 14-year-old male Maine Coon cat, in good condition, received FRONTLINE SPRAY POMPE 1.5 mL (BN: S01101A, Exp. date: MAR 2021) administered topically by the owner on 04 JUL 2019: unclear administered dose, mentioned to be a few less than recommended dosage (nos) for the first time. After product administration, during the night of 04 JUL 2019, the animal experienced intense fever, tongue outside the mouth (encoded as "Respiratory distress" into Veddra), drooling, and its heart "nearly exploded" (encoded as "Tachycardia" into Veddra). No further information was available at the time of this report. Note: The cats lives exclusively indoors but was infested with fleas by a dog that the owner took into her home. Note 2 : case considered as serious due to owner description (the cat heart "nearly exploded").
15-Jul-2019	UAE; 19FR000858; -; France	Species: Canine Breed: Bernese Mountain Dog Sex: U Sex qualifier: Unknown Age: 8.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: FRONTLINE PETCARE DIFFUSEUR INSECTICIDE ET ACARICIDE POUR L'HABITAT; Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	03-Jul-2019	03-Jul-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy: As reported by the animal's owner, Gibraltar, a 8-year-old Bernese Mountain dog in good condition received one pipette of FRONTLINE COMBO SPOT-ON CHIEN XL (BN: R60101AX, Exp. date: DEC 2019) administered topically by the owner between the shoulders on 03 JUL 2019 for flea treatment. 10 FRONTLINE PETCARE DIFFUSEURS INSECTICIDE ET ACARICIDE (BN: 337G2, Exp. date: NOV 2020) were used on 06 JUL 2019 for the treatment of the environment. After treatment (unknown time to onset), fleas were still visible on the animal. No further information was available at the time of this report. Note: two cats (Mirabelle, a 1-year-old female European cat and Gratouille, a 4-year-old male European cat) received each one pipette of FRONTLINE COMBO CHAT (BN and exp. date: unknown) administered topically by the owner on 03 JUL 2019 and no flea was still visible on the two cats after treatment.
16-Jul-2019	UAE; 19FR000874; -; France	Species: Feline Breed: Feline Other Sex: F Sex qualifier:	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other	02-Jul-2019	04-Jul-2019	2 Day(s)	D-D	Suspected Adverse Event: As reported by the animal's owner, a 1.5-year-old female crossbred cat, 2 to 3 kg, in good condition, received one pipette of FRONTLINE SPOT-ON CHAT (BN and exp. date: unknown, product unsubstantiated) administered at the base of the neck between the shoulders by the owner on 02 JUL

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 104 of 867

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00111

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Unknown Age: 1.50 Year(s) Weight: 2 - 3 kg				products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company					2019. 2 days after product administration, on 04 JUL 2019, the animal experienced application site hairloss and pink bottom of the lower lip. The owner also reported that the cat had licked itself a lot. No further information was available at the time of this report. Note: the owner mentioned administration of MILBEMAX on 07 JUL 2019.
18-Jul-2019	UAE; 19FR000881; -; France	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	Jun-2019*	Jun-2019*	11 Day(s)	D-D	LACK OF EFFICACY case: As reported by the owner, a dog (age, sex, breed and weight unknown) had received topically FRONTLINE COMBO SPOT ON CHIEN S (1 dose, BN and exp. date: NOS) administered by the owner in JUN 2019 (approx. date). Then (time to onset nos), the animal still had fleas. No further information at the time of the report. Note: the owner reported that the dog was washed up and dried before the administration of the product. Plus, the animal is brushed daily, the housing is healthy and the dog's basket is washed regularly.
21-Jul-2019	UAE; 19FR000893; -; France	Species: Canine Breed: Retriever (Labrador, Black) Sex: F Sex qualifier: Unknown Age: 4.50 Year(s) Weight: 35 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: DERMIPRED; Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	08-Jul-2019	12-Jul-2019	4 Day(s)	D-C	Suspected Adverse Event: As reported by the animal's owner, a 4.5-year-old intact female Labrador dog, 35 kg, received one pipette of FRONTLINE COMBO SPOT ON CHIEN L (BN: R61912AX, Exp. date: AUG 2020) administered topically by the owner at the base of the neck between the shoulders on 08 JUL 2019 for flea treatment. 4 days after product administration, on 12 JUL 2019, the animal experienced severe burnings, irritations (similar as a sunburn), and hair loss starting from the collar and spreading until 20 cm in length and 10 cm in width. A beginning of necrosis was observed at the base of each hair. The animal was slightly lethargic. It was brought to the vet on 18 JUL 2019 and was treated with Kesium 625 mg (0.75 tablet bid for 10 days) and Dermaflon solution (3 times per day). Ultrasound was scheduled on 24 JUL 2019 because the animal's abdomen was slightly "swollen" (coded as "Distension of abdomen" into Veddra). The reaction was ongoing at the time of this report. Note: the animal was treated every 3 months with a product from the FRONTLINE (unspecified) range. It had been under DERMIPRED (10 mg/day) for 2 years because of Addison disease.
23-Jul-2019	UAE; 19FR000909; -; France	Species: Feline Breed: European Sex: M Sex qualifier: - Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPRAY Other products used: FIPRONIL 6.01% / PERMETHRIN 44.88% SPOT ON SOLUTION; Route: Topical / Cutaneous Was the product used ok?: No (Low dose)	16-Jul-2019	17-Jul-2019	1 Day(s)	D-B	FR-ANMV-19 CPVL 01021: D0: European cat applied with both 1 pipette of FRONTLINE TRI-ACT SOLUTION POUR SPOT-ON POUR CHIENS 20 - 40 KG and spray of FRONTLINE SPRAY. D1: it displayed muscle tremor. Afternoon (phonecall), at vet clinic, after washing, it also showed tonic seizure. Evening (second phonecall) still tremors despite diazepam administration. Also hypothermia. D2 noon (third phonecall): cat better, no more tremors since midnight, but displaying behavioral trouble, excessive grooming. Duration of reaction: < or = 24 hours. Duration of reaction (precision): ongoing (24 hours). Reason for treatment: fleas. Treatment of SAR: washing and diazepam. Investigations: none. Outcome of SAR: Unknown. FRONTLINE TRI-ACT SOLUTION POUR SPOT-ON POUR CHIENS 20 - 40 KG () : 1 pipette; duration: once; onset time: 12-24 hours. FRONTLINE SPRAY POMPE () : 1 spraying; duration: once; onset time: 12-24 hours

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 105 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00112

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
25-Jul-2019	UAE; 19FR000913; -, France	Species: Feline Breed: European Sex: F Sex qualifier: Neutered Age: 1.00 Year(s) Weight: 3 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Species not indicated / recommended)	25-Jun-2019	27-Jun-2019	2 Day(s)	D-C	FR-ANMV-19 CPVL 00886: D0: An European cat was accidentally administered with FRONTLINE SPOT ON CHIEN XL. It ran away for 48 hours. D2: at its return, it displayed trembling. Vet examination: washing, diazepam, fluid therapy. D3: slight improvement of trembling but normal consciousness, appetite and movements. Duration of reaction: < or = 7 days Duration of reaction (precision): Ongoing (< 24 h after return). Reason for treatment: Preventive. Treatment of SAR: washing, diazepam, fluid therapy. Outcome of SAR: Unknown
24-Jul-2019	UAE; 19FR000927; -, France	Species: Canine Breed: Yorkshire Terrier Sex: M Sex qualifier: Neutered Age: 5.00 Year(s) Weight: 3.5 kg	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	Jul-2017*	Jul-2017*	0 Day(s)	D-D	Suspected Lack of Efficacy: As reported by the animal's owner, Xeryus, a 5-year-old neutered male Yorkshire dog, 3.5 kg, in good condition, received FRONTLINE SPRAY POMPE (BN: R02005A, Exp. date: MAR 2019) administered topically by the owner in JUL 2017 for flea treatment. After product administration (unknown time to onset), the animal experienced a complete lack of efficacy (no further details provided). No further information was available at the time of this report. This case is linked with the case 19FR928: SLOE in a cat from the same household after administration of the same product.
24-Jul-2019	UAE; 19FR000928; -, France	Species: Feline Breed: Persian (No Further Description) Sex: F Sex qualifier: Neutered Age: 12.00 Year(s) Weight: 4 kg	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	Jul-2017*	Jul-2017*	0 Day(s)	D-D	Suspected Lack of Efficacy: As reported by the animal's owner, Betty, a 12-year-old spayed female Persian cat, 4 kg, in good condition, received FRONTLINE SPRAY POMPE (BN: R02005A, Exp. date: MAR 2019) administered topically by the owner in JUL 2017 for flea treatment. After product administration (unknown time to onset), the animal experienced a complete lack of efficacy (no further details provided). No further information was available at the time of this report. This case is linked with the case 19FR927: SLOE in a dog from the same household after administration of the same product.
25-Jul-2019	UAE; 19FR000929; -, France	Species: Feline Breed: European Sex: M Sex qualifier: Neutered Age: 1.00 Year(s) Weight: 7.6 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	08-Jul-2019	Jul-2019*	23 Day(s)	D-D	Suspected Adverse Event: As reported by the animal's owner, Loki, a 1-year-old neutered male European cat, received one pipette of FRONTLINE COMBO SPOT-ON CHAT (BN: S41403AW, Exp. date: OCT 2021) administered topically between the shoulders by the owner on 08 JUL 2019 (mentioned to be preventive treatment). After product administration (unknown time to onset), the animal experienced scratching with fleas observed on the animal. No further information was available at the time of this report.
31-Jul-2019	UAE; 19FR000937;	Species: Canine Breed: Maltese	1	1	0	Product used: FIPRONIL SPOT	20-Jun-2019	23-Jun-2019	3 Day(s)	D-C	FR-ANMV-19 CPVL 00864: D0: 4.7-kg Maltese dog applied with FRONTLINE SPOT ON CHIEN M (for 10-20 kg dog). D3: it

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 106 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00113

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	-; France	Sex: M Sex qualifier: - Age: 8.00 Year(s) Weight: 4.7 kg				ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Overdose)					displayed apathy. D4: at presentation, apathy, stiff gait /walking on tiptoes. No tremor, normal body temperature, no digestive sign. Duration of reaction: < or = 24 hours. Duration of reaction (precision): < 24 hours. Reason for treatment: preventive. Outcome of SAR: Unknown
30-Jul-2019	UAE; 19FR000959; -; France	Species: Canine Breed: Canine various breeds Sex: X Sex qualifier: Unknown Age: 6.50 Month(s) Weight: 2 - 40 kg	8	8	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	15-Jul-2019	15-Jul-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy: As reported by the animal's owner, 8 dogs of various breeds (Chihuahua, Pug, German Shepherd), aged between 6.5 months and 4 years, weighing 2 or 7-8 kg or 30-40 kg, in good condition, received each FRONTLINE SPRAY POMPE (BN: T00102A, Exp. date: DEC 2021) administered topically by the owner all over the body on 15 JUL 2019 for flea treatment (unknown dose, number of sprays per animal). After product administration (unknown time to onset), fleas were still visible on the animals. The SLOE was ongoing at the time of this report. Note: the owner already administered such product before (every month) without any reaction/lack of efficacy.
31-Jul-2019	UAE; 19FR000960; -; France	Species: Feline Breed: European Sex: M Sex qualifier: - Age: 2.00 Year(s) Weight: 3.2 kg	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	18-Jul-2019	29-Jul-2019	11 Day(s)	D-C	Suspected Adverse Event: As reported by the animal's owner, Nougat, a 2-year-old intact male European cat, 3.2 kg, in good condition, received one pipette of FRONTLINE SPOT-ON CHAT (BN: T20A109AW, Exp. date: DEC 2021) administered topically between the shoulders by the owner on 18 JUL 2019 (to treat itching). 11 days after product administration, on 29 JUL 2019, the animal experienced lethargy, anorexia, staggering, and was unable to stand up. The signs were ongoing at the time of this report. Note: the animal had never been treated with a parasiticide before.
05-Aug-2019	UAE; 19FR000971; -; France	Species: Feline Breed: European Sex: M Sex qualifier: Neutered Age: 1.00 Year(s) Weight: 5 - 8 kg	2	2	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	16-Jul-2019	16-Jul-2019	0 Day(s)	D-D	Suspected Lack of Efficacy: As reported by the animal's owner, two neutered male European cats (Gnocky, a 1-year-old cat, 5 kg, and Bouly, a 8-year-old cat, 9 kg) in good condition received each one pipette of FRONTLINE SPOT-ON CHAT (BN: S21812ax, Exp. date: NOV 2021) administered topically by the owner between the shoulders on 16 JUL 2019 for flea treatment. After product administration, the animals experienced a lack of efficacy (NOS). No further information was available at the time of this report.
02-Aug-2019	UAE; 19FR000972; -; France	Species: Feline Breed: British Shorthair Sex: X Sex qualifier: Unknown Age: 8.00 Month(s) Weight: 2 - 9 kg	6	6	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: FIPRONIL SPRAY; UNKNOWN	26-Jul-2019	01-Jul-2019*	N/A	D-D	Suspected Lack of Efficacy: As reported by the animal's owner, 6 British Shorthairs cats (Ody), 8 month old, 3.5 kg; Olga, 8 months old, 3.5 kg; Ilda, 7 years old, 3.4 kg; Gattino, 9 years old, 9 kg; Ely Mai, 11 years old, 4.5 kg; Tabata, 17 years old, 2 kg) live in the same household. At the beginning of JUL 2019, because she saw fleas on her six animals, the owner administered 1 pipette of an unknown product (but is was not FRONTLINE) to the four oldest cats and also administered FRONTLINE SPRAY POMPE 250 mL (BN: R00406A; exp. date: DEC 2018) topically all over the body of

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 107 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00114

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						FLEA PRODUCT; Route: Topical / Cutaneous Was the product used ok?: Unknown to Company					the 6 cats (6 sprays for the youngest animals and 12 sprays for the oldest). Since she saw no efficacy, the owner administered one pipette of FRONTLINE COMBO SPOT ON CHAT (BN and exp. date: unknown) on 16 JUL 2019 to the 6 animals. After product administration (unknown time to onset), she still continued to see alive fleas on her animals. No further information was available at the time of this report. Note: concomitantly to the administration of FRONTLINE COMBO SPOT-ON CHAT, the owner vacuumed all corners of her house, cleaned the pillows, and sprayed a flea product on the baskets. The animals live indoors. Off-label dose: underdosage: FRONTLINE SPRAY POMPE 1.5 ml was used in this case. But even if the 1.5 ml dosage was used, the youngest animals (3.5 kg) should have received at least 7 sprays and Gattino (9 kg) should have received at least 18 sprays. The product was however overdosed in the other adult animals. UPDATE ON 15 SEP 2019: FRONTLINE COMBO SPOT ON CHAT (BN and exp. date: unknown) was first administered on 26 JUL 2019 and then readministered on 15 AUG and 15 SEP 2019 to the 6 animals but without any improvement. Fleas reappeared 2 weeks after each treatment. At the time of this report, after use of a special comb for fleas, the owner did not find any flea feces but alive fleas on her animals. Note: the animals from a familial breeding had been assembled in one room since the
08-Aug-2019	UAE; 19FR000979; -; France	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	01-Aug-2019	08-Aug-2019	1 Week(s)	D-D	Suspected Lack of Efficacy: As reported by the animal's owner, a cat in good condition received one pipette of FRONTLINE COMBO SPOT-ON CHAT (BN and exp. date: unknown) administered topically by the owner in the neck on 01 AUG 2019 for flea treatment. 7 days after product administration, on 08 AUG 2019, the animal still had fleas. No further information was available at the time of this report.
11-Aug-2019	UAE; 19FR000988; -; France	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	10-Aug-2019*	10-Aug-2019*	0 Day(s)	D-B	Suspected Adverse Event: As reported by the animal's owner, a cat (unknown signalment and health condition prior to product administration) received one pipette of FRONTLINE SPOT-ON CHAT (BN and exp. date: unknown) administered topically in the neck by the owner on an unknown date (10 AUG 2019 was chosen by default). After product administration (unknown time to onset), the animal experienced severe convulsions and was hospitalised in emergency in a clinic (unknown attending vet). No further information was available at the time of this report. Note: it was the first administration of FRONTLINE SPOT-ON CHAT to the animal.
12-Aug-2019	UAE; 19FR001002; -; France	Species: Feline Breed: Feline various breeds Sex: M Sex qualifier: Neutered Age: 5.00 Year(s)	2	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other	21-Jul-2019	11-Aug-2019*	3 Week(s)	D-D	Suspected Lack of Efficacy: As reported by the animal's owner, two neutered male cats, 5 kg (a 5-year-old Birman and a 7-year-old Persian), in a good condition, received one pipette of FRONTLINE COMBO SPOT-ON CHAT (BN: T40116DW, Exp. date: DEC 2021) administered topically by the owner at the base of the neck on 21 JUL 2019 for prevention. 3 weeks after product administration, fleas appeared on the Birman cat. A new pipette of FRONTLINE COMBO SPOT ON CHAT was administered to the Birman cat on

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 108 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00115

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: 5 kg				products Route: Topical / Cutaneous Was the product used ok?: Yes					11 AUG 2019. No further information was available at the time of this report. Note: before administration of FRONTLINE COMBO SPOT ON CHAT, the animals were wearing a collar.
16-Aug-2019	UAE; 19FR001007; -, France	Species: Feline Breed: European Sex: X Sex qualifier: Mixed Age: 11.00 Month(s) Weight: 4-5 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: PO-Oral Was the product used ok?: No (Route not indicated / recommended)	06-Aug-2019	07-Aug-2019	1 Day(s)	D-D	FR-ANMV-19 CPVL 01104: D0 evening: European cat administered orally with FRONTLINE COMBO SPOT-ON CHAT (stray cat rescued by animal shelter). D1 morning: it displayed nausea, aggressive behaviour (almost impossible to handle). After examination: no salivation, no oral lesion, no vomiting. Animal discharged that day. Duration of reaction: < or = 12 hours. Duration of reaction (precision): < 12 hours. Reason for treatment: preventive. Treatment of SAR: none. Outcome of SAR: Favorable. FRONTLINE COMBO SPOT-ON CHAT () : 1 pipette; duration: Once; onset time: < 12 hours.
19-Aug-2019	UAE; 19FR001010; -, France	Species: Canine Breed: Terrier (Jack Russell) Sex: M Sex qualifier: - Age: 1.50 Year(s) Weight: 8.2 kg	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Low dose)	07-Aug-2019	07-Aug-2019	0 Day(s)	D-C	FR-ANMV-19 ANMV 01663: A 1.5 year old Jack Russel Terrier dog received for the 1st time FRONTLINE SPRAY POMPE 0.5 ML (6 sprayings) on 07-Aug-2019, 05:30 pm. Around 09:00 pm, the dog presented with weakness, vomiting, drunken gait and breathing difficulty. Around midnight, the dog showed facial pruritus and swollen lips. At blood analyses: increase of liver parameters and lymphocytosis. The dog received SOLUMEDROL 40 and HISTACALMINE at midnight. The following day morning (09:45), the dog was cured.
19-Aug-2019	UAE; 19FR001012; -, France	Species: Feline Breed: European Sex: F Sex qualifier: Unknown Age: 9.00 Year(s) Weight: 3 - 4 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	12-Aug-2019	19-Aug-2019*	1 Week(s)	D-D	Suspected Lack of Efficacy: As reported by the animal's owner, a 9-year-old Female European cat, between 3 and 4 kg, in good condition, received one pipette of FRONTLINE COMBO SPOT-ON CHAT (BN: T40116DW, Exp. date: DEC 2021) administered topically by the owner between the shoulders on 12 AUG 2019 for flea treatment. After product administration (unknown time to onset, mentioned by default as 7 days, as the reported on 19 AUG 2019), the animal was still scratching and fleas were still present on the animal. No further information was available at the time of this report. Note: the animal lives with a dog at least partially outside. The owner was used to administer FRONTLINE (unspecified) to her animals without any problem. This case is linked with the case 19FR1013: non serious SLOE in a dog from the same household after administration of FRONTLINE TRI-ACT POUR CHIENS.
20-Aug-2019	UAE; 19FR001015; -, France	Species: Feline Breed: Feline (unknown) Sex: X Sex qualifier: Unknown Age: 1.00 Year(s) Weight: 2.5 - 3 kg	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products	22-Jul-2019	29-Jul-2019	1 Week(s)	D-D	Suspected Lack of Efficacy: As reported by the animal's owner, two 1-year-old cats (a male weighing 3 kg) and a female weighing 2.5 kg), in good condition, received one pipette of FRONTLINE COMBO SPOT-ON CHAT (BN: T40116DW, Exp. date: DEC 2021) administered topically by the owner between the shoulders for flea treatment on 22 JUL 2019. 1 week after product administration, on 29 JUL 2019, fleas were visible again on the animals. No further information was available at the time of this report. Note: the owner

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 109 of 867

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00116

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Route: Topical / Cutaneous Was the product used ok?: Unknown to Company					had treated the animals' environnement against fleas (unknown product).
23-Aug-2019	UAE; 19FR001025; -, France	Species: Feline Breed: European Sex: M Sex qualifier: Neutered Age: 1.00 Year(s) Weight: 4 kg	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	20-Aug-2019	23-Aug-2019*	3 Day(s)	D-D	Suspected Lack of Efficacy: As reported by the animal's owner, Happy a 1-year-old neutered male European cat, 4 kg, in good condition, received one pipette of FRONTLINE SPOT-ON CHAT (BN: S21812AX, Exp. date: NOV 2021) administered topically by the owner at the base of the neck on 20 AUG 2019 for flea treatment (fleas were seen on the animal prior administration). On 23 AUG 2019 (time of reporting), no improvement was observed after product administration (suspicion of lack of efficacy by the owner). No further information was available at the time of this report.
24-Aug-2019	UAE; 19FR001027; -, France	Species: Canine Breed: Khorthal Sex: M Sex qualifier: Unknown Age: 8.00 Month(s) Weight: 28 - 33 kg	2	2	0	Product used: FIPRONIL SPRAY Other products used: FIPRONIL SPOT ON DOG; Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	01-Mar-2019*	01-Mar-2019*	N/A	D-D	Suspected Lack of Efficacy: As reported by the animal's owner, two male Khorthals dogs (the first aged 5 years and weighing 33 kg and the second aged 8 months and weighing 28 kg), in good condition, received each one pipette of FRONTLINE SPOT-ON CHIEN (product unsubstantiated) (BN and exp. date: unknown) administered once monthly by the owner from early spring until around 13 AUG 2019 for flea treatment. Furthermore, the two animals were administered with FRONTLINE SPRAY (BN: S00906A; exp. date: MAR 2021) each time they went for a walk. After product administration (unknown time to onset), fleas were still visible on the animals. No further information was available at the time of this report. Note: The two animals live outdoors. The owner treated the animals' living environment with a fogger (unspecified) and did not observe any fleas anymore at home.
28-Aug-2019	UAE; 19FR001035; -, France	Species: Feline Breed: Persian (No Further Description) Sex: X Sex qualifier: Unknown Age: 1.00 Year(s) Weight: 2 - 4 kg	3	3	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Others)	23-Aug-2019	28-Aug-2019*	5 Day(s)	D-D	Suspected Lack of Efficacy: As reported by the animal's owner, three intact Persian cats, one male and 2 females, aged from 1 to 4 years, 2 to 4 kg, in good condition, received each one pipette of FRONTLINE SPOT-ON CHAT (BN: S21717AL, Exp. date: OCT 2021) administered topically by the owner at the base of the neck and of the tail on 23 AUG 2019 because of fleas present on the animals. After product administration, fleas were still visible on the animals. On 28 AUG 2019, i.e. 5 days after application, the owner reported a lack of efficacy. No further information was available at the time of this report. Note: considered as off-label use (recommended application site is only between shoulders).
06-Sep-2019	UAE; 19FR001088; -, France	Species: Feline Breed: European Sex: F Sex qualifier: Not applicable Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used	11-Aug-2019	14-Aug-2019	3 Day(s)	D-C	FR-ANMV-19 CPVL 01143: D0: An European cat was administered with FRONTLINE SPOT ON CHAT. D3 evening: it displayed myoclonus, hyperaesthesia. Emergency vet examination: hospitalization, fluid therapy. D4: discharge in a good health conditions. Duration of reaction: < or = 24 hours. Duration of reaction (precision): 15/08/19. Reason for treatment: preventive. Treatment of SAR: Hospitalization, Fluid therapy. Outcome of SAR: Favorable. FRONTLINE SPOT ON CHAT () : 1 pipette; duration: Once; onset time: < 3 days.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 110 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00117

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						ok?: Unknown to Company					
03-Sep-2019	UAE; 19FR001097; -; France	Species: Feline Breed: Siberian Cat Sex: F Sex qualifier: Neutered Age: 9.00 Year(s) Weight: 4.3 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: FLEA COLLAR (UNKNOWN); Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	28-Aug-2019	28-Aug-2019	0 Day(s)	D-D	Suspected Lack of Efficacy: As reported by the animal's owner, Fidji, a 9-year-old spayed female Siberian cat, 4.3 kg, in good condition, received one pipette of FRONTLINE COMBO SPOT-ON CHAT (BN: S41413BW, Exp. date: OCT 2021) administered topically by the owner between the shoulders on 28 AUG 2019 for flea treatment. The same day, a lack of efficacy was reported. No further information was available at the time of this report. Note: a flea collar (unknown) was put on the animal on 28 AUG 2019 concomitantly with FRONTLINE COMBO. The owner was used to treat the animal's environment with a fogger and a spray from another brand (Biocanina) every 10 days.
10-Sep-2019	UAE; 19FR001105; -; France	Species: Canine Breed: Belgian Tervueren Sex: U Sex qualifier: Unknown Age: 7.00 Month(s) Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	01-Jul-2019*	07-Jul-2019*	6 Day(s)	D-D	Suspected Adverse Event: As reported by the owner, Menino du Ribaudeau, a Belgian Tervueren dog, born on 01 JAN 2019, received FRONTLINE COMBO SPOT ON (product unsubstantiated) (BN and exp. date: unknown) administered on an unknown date (01 JUL 2019 was chosen by default). After product administration (unknown time to onset), the animal experienced large application site depigmentation and hair loss. On approx. 13 JUL 2019, the animal was brought to the vet: the dog experienced hair loss on the line of the back. Hairs were sampled and sent to a lab. Mycological analysis (direct examination, mycology and dermatophytes) was negative. At the time of this report, hairs were regrowing slowly. Note 1: the product was not sold by the vet to the owner, thus it is unknown which product was used and if it was administered correctly. Note 2: After the first visit (for dermatological examination and samplings), the vet had never heard from the animal.
16-Sep-2019	UAE; 19FR001114; -; France	Species: Feline Breed: Feline (unknown) Sex: M Sex qualifier: - Age: 2.50 Year(s) Weight: 4.85 kg	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Indication not indicated / recommended)	15-Aug-2019	16-Aug-2019	1 Day(s)	D-C	FR-ANMV-19 CPVL 01152: D0: cat applied with FRONTLINE SPRAY POMPE 0,5 ML. D2: presented with anorexia (since D1), apathy. Empty stomach. Urinalysis yielded increased urine concentration, glucosuria, proteinuria (dipstick). Final outcome not known. Duration of reaction: < or = 24 hours. Duration of reaction (precision): ongoing (24 hours). Reason for treatment: harvest mite. Treatment of SAR: fluid therapy, supportive care (NOS). Investigations: Renal parameters pending. Cat with outdoor access. Outcome of SAR: Unknown. FRONTLINE SPRAY POMPE 0,5 ML () : 20 pump activations; duration: Once; onset time: < 24 hours.
17-Sep-2019	UAE; 19FR001142; -; France	Species: Feline Breed: Feline (unknown) Sex: M Sex qualifier: Unknown Age: -	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other	15-Sep-2019*	17-Sep-2019*	2 Day(s)	D-C	Suspected Lack of Efficacy: As reported by the animal's owner, a male cat (unknown signalment and health condition prior to product administration) received one pipette of FRONTLINE SPOT-ON CHAT (BN: S40506AW, Exp. date: FEB 2021) administered topically in the neck by the owner around 15 SEP 2019 for flea treatment. About 2 days after product administration, around 17 SEP 2019, the animal experienced a lack of efficacy.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 111 of 867

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

v1.2

ED_005739D_00014390-00118

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: Unknown				products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company					The animal was so bitten by fleas that it developed eczema, crusts, and wounds everywhere. It was brought to the vet (unknown vet) who administered antibiotics, antiinflammatories, and a new flea product (unspecified). No further information was available at the time of this report. Note: the dermatological signs were not coded into Veddra as they were considered to be the results of flea infestation.
23-Sep-2019	UAE; 19FR001143; -; France	Species: Canine Breed: German Shepherd Dog Sex: M Sex qualifier: - Age: 1.00 Year(s) Weight: 45 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: PO-Oral Was the product used ok?: No (Species not indicated / recommended)	21-Aug-2019	21-Aug-2019	0 Day(s)	D-D	FR-ANMV-19 CPVL 01202: During daytime (in absence of owner), German Shepherd Dog had ingested accidentally 2 pipettes of FRONTLINE COMBO SPOT-ON CHAT. When owner returned home in the evening, the dog had displayed diarrhoea. Good general condition. Final outcome not known. Duration of reaction: < or = 12 hours. Duration of reaction (precision): ongoing (< 8 hours). Reason for treatment: (accidental). Outcome of SAR: Unknown. Authority comment: FRONTLINE COMBO SPOT-ON CHAT () : 2 pipettes; duration: Once; onset time: < 8 hours.
23-Sep-2019	UAE; 19FR001144; -; France	Species: Feline Breed: European Sex: F Sex qualifier: Not applicable Age: 3.50 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	12-Sep-2019	12-Sep-2019	0 Day(s)	D-B	FR-ANMV-19 CPVL 01335: D0: European cat applied with FRONTLINE SPOT ON CHAT. Later that day : onset of epileptic seizures. D1 morning at vet examination: cat trembling. After washing and only one diazepam injection, animal in pretty better condition. Note : also dog in same house, treated in the same time with "pipettes for dogs" (permethrin ?), but no contact with cat. Duration of reaction: < or = 12 hours. Duration of reaction (precision): ongoing (12 hours). Reason for treatment: fleas. Treatment of SAR: Washing and Diazepam once. Investigations: Permethrin based pipette ? Outcome of SAR: Unknown. Authority comment: FRONTLINE SPOT ON CHAT () : 1 pipette; duration: once; onset time: < 12 hours.
24-Sep-2019	UAE; 19FR001154; -; France	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: MILBEMAX COMPRIMES PELLICULES POUR CHATS; Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	01-Sep-2019	02-Sep-2019	1 Day(s)	D-C	FR-ANMV-19 CPVL 01283: D0 late evening: A cat was administered with FRONTLINE COMBO SPOT-ON CHAT and MILBEMAX COMPRIMES PELLICULES POUR CHATS. Within a few hours (D1, 1 a.m.), it displayed ataxia. Note: phone call before examination by the vet, poorly reliable case. Duration of reaction: < or = 6 hours. Duration of reaction (precision): Ongoing (A few hours). Reason for treatment: Preventive. Outcome of SAR: Unknown. Authority comment: FRONTLINE COMBO SPOT-ON CHAT () : 1 pipette; duration: Once; onset time: A few hours. MILBEMAX COMPRIMES PELLICULES POUR CHATS () : ?; duration: Once; onset time: A few hours.
23-Sep-2019	UAE; 19FR001156; -; France	Species: Feline Breed: Feline (unknown)	1	1	0	Product used: FIPRONIL 10%/S	26-Aug-2019*	26-Aug-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy: As reported by the animal's owner, a male cat (unknown signalment and health condition prior to product administration), received one pipette of FRONTLINE

N/A signifies the information for this field is either not available or not applicable

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

Report printed on 25-Oct-2019 at 8:39:59PM

*indicates Approximate date or weight

Page 112 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00119

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex: M Sex qualifier: Unknown Age: - Weight: Unknown				METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company					COMBO SPOT-ON CHAT (BN and exp. date: unknown) administered topically by the owner around 26 AUG 2019 for flea treatment. After product administration (unknown time to onset), fleas were still visible on the animal. No further information was available at the time of this report.
27-Sep-2019	UAE; 19FR001178; -, France	Species: Feline Breed: European Sex: M Sex qualifier: Unknown Age: 8.00 Year(s) Weight: 7 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	10-Sep-2019	13-Sep-2019	3 Day(s)	D-C	Suspected Adverse Event: As reported by the animal's owner, a 8-year-old male European cat, 7 kg, in good condition, received one pipette of FRONTLINE COMBO SPOT-ON CHAT (BN: TK0116D, Exp. date: DEC 2021) administered topically in the neck by the owner on 10 SEP 2019. 3 days after product administration, on 13 SEP 2019, the animal experienced apathy and decreased appetite (usually the animal is alert). At the time of this report, on 27 SEP 2019, the animal's health condition had not improved.
24-Sep-2019	UAE; 19HU000022; -, Hungary	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	Apr-2019*	Aug-2019*	0 Day(s)	D-D	Suspected lack of efficacy: as reported by the animal owner, a cat unknown age, gender, breed and weight, received FRONTLINE COMBO SPOT-ON MACSKA A.U.V. 0.5 ml in APR, JUN and AUG 2019 as prevention of tick infection. In the last time, a lot of ticks were found on the cat, more of them on the neck at the application site.
01-Jul-2019	UAE; 19IT000089; -, Italy	Species: Feline Breed: European Sex: M Sex qualifier: Neutered Age: 6.00 Year(s) Weight: 7.7 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	21-Jun-2019	22-Jun-2019	N/A	D-B	As reported by the Owner, a cat, male, European, 6 years old, 7,7 kg weight, neutered, received 1 dose of Frontline Combo Spot On Cats administered by the Owner on 21 June 2019. 1 day after product administration the animal experienced asthenia, anorexia, and it couldn't get up. The owner brought his cat to the Vet and the animal made exams. Analysis/tests as ultrasound, radiography and blood exams were performed and showed lack of potassium. An integrative and anti-inflammatory therapy was performed for 6 days but the results were complete body paralysis and lack of appetite. The owner reported that he always administrated Frontline Spot On Cats on his cat. This was the first time that he administrated Frontline COMBO Spot On Cats. The day before product application the cat was out of the home and it can't be excluded poisoning

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 113 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00120

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
09-Jul-2019	UAE; 19IT000096; -, Italy	Species: Canine Breed: Beagle Sex: M Sex qualifier: Unknown Age: 9.00 Month(s) Weight: Unknown	-	-	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	19-Jun-2019	19-Jun-2019*	N/A	D-D	As reported by the Owner, a dog, male, Beagle, 9 months old received 1 dose of Frontline Combo Spot On Dogs M, batch number R61917CL, expiry date August 2020 administered by the owner every months from Feb 2019 until 19 June 2019, that was administered late, as reported by the owner. After product administration the animal experienced still fleas on its hair and for this reason it used to scratch itself a lot. The animal also received during this months collar Scalibor. On 10 June 2019 the owner brought his dog in countryside house.
22-Jul-2019	UAE; 19IT000100; -, Italy	Species: Canine Breed: Shih Tzu Sex: F Sex qualifier: Unknown Age: 3.00 Year(s) Weight: 5.5 kg	-	-	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	Mar-2019*	01-Mar-2019*	N/A	D-D	As reported by the Owner, a dog, female, Shih Tzu, 3 years old, 5,5 kg weight, received 1 dose of Frontline Combo Spot On S, batch number R60524AL administered by the Owner since the end of March every 3 weeks following Vet advice. After product administration the animal experienced still fleas on its hair. As reported by the owner the dog is bathed every month. In the same house there are 2 cats that are both treated regularly (batch number of their product: T40212CW).
23-Jul-2019	UAE; 19IT000101; -, Italy	Species: Canine Breed: Yorkshire Terrier Sex: M Sex qualifier: Unknown Age: 11.00 Year(s) Weight: 10 kg	-	-	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	20-Jul-2019	20-Jul-2019	N/A	D-D	As reported by the Owner, a dog, Yorkshire, male, 11 years old, 10 kg weight received 1 dose of Frontline Combo Spot-On Dogs 2-10 kg, batch number S61405A, exp. date 05/2021, cutaneously, between the shoulders, administered by the owner on 20 July 2019. The owner use to administer Frontline Combo Spot-On Dogs 2-10 kg every months. After product administration the animal experienced already fleas and ticks on its skin. As reported by the owner the animal use to stay also outside closed to green areas. The owner suspect lack of efficacy.
02-Aug-2019	UAE; 19IT000103; -, Italy	Species: Feline Breed: European Sex: F Sex qualifier: Neutered Age: 3.00 Year(s) Weight: -	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	Aug-2018*	Aug-2018*	N/A	D-D	As reported by the owner, a cat, European, female, neutered, 3 years old received 1 dose of Frontline Combo Spot On Cats, topically, administered by the owner on August 2018. After product administration (unknown how many time occurred between product administration and reaction) the animal experienced alopecia (3 cm diameter). Slowly the hair is growing again. The cat is really sensitive and delicate. In the past the cat received same product (frontline Combo Spot on cats) without any reaction

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 114 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00121

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
11-Sep-2019	UAE; 19IT000111; -; Italy	Species: Canine Breed: Setter (English) Sex: U Sex qualifier: Unknown Age: Adult Weight: Unknown	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	01-Jul-2019	01-Jul-2019	N/A	D-D	As reported by the owner, a dog, Setter, adult, received Frontline Spray administered by the owner on 1 July 2019. 1 day after product administration the animal experienced already fleas on its skin. The owner suspected lack of efficacy.
17-Sep-2019	UAE; 19IT000112; -; Italy	Species: Feline Breed: Domestic Longhair (Crossbreed) Sex: F Sex qualifier: Unknown Age: 11.00 Year(s) Weight: 5 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	24-May-2019	24-Aug-2019	N/A	D-D	As reported by the owner, two cats, male (7 years old, 7.5 kg weight) and female (11 years old, 5 kg weight), mixed breed longhair, received 1 dose of Frontline Combo spot on Cats, cutaneously administered by the owner on 24 August 2019. After product administration animals experienced already ticks on their skin. In particular for both cats, the owner found 1 tick on their skin on 16 September 2019 and 1 tick one week before (not specified the correct day, around 9 September 2019). The owner suspected lack of efficacy.
23-Sep-2019	UAE; 19IT000113; -; Italy	Species: Feline Breed: European Sex: M Sex qualifier: Neutered Age: 7.00 Year(s) Weight: 8 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	10-Sep-2019	11-Sep-2019	N/A	D-D	As reported by the owner, a cat, male, European, 7 years old, 8 kg weight, neutered, received 1 dose of Frontline Combo spot on Cats, topically, intrascapular, administered by the owner on 10 September 2019. 1 day after product administration the animal experienced alopecia (2-3 cm) on the application site. As reported by the owner the cat is recovering.
31-Jul-2019	UAE; 19JP000138; Tokyo; Japan	Species: Canine Breed: Poodle (Toy) Sex: M Sex qualifier: Neutered Age: 4.00 Year(s) Weight: 2.5 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	Jul-2017*	Oct-2017*	N/A	D-D	As reported by the veterinary nurse, FRONTLINE PLUS DOG S (Lot number: unknown, Expiry date: unknown, Topical, 1 pipette) was administered once 2 years ago and once around last summer to a 4-year-old, male, neutered, toy poodle (body weight 2.5 kg) by the owner. Around October to November 2017, the dog developed thinning of the hair throughout the body. The dog is groomed regularly and it was considered that the event was caused by the use of an electric hair clipper. However, the owner subsequently read the package insert of the product, which indicates that a hair loss may develop after using the drug. The owner told the veterinarian that the thinning of the hair might have been caused by the administration of the product. Although there was no hair loss at the application site, discoloration of the hair (from light brown to white) was observed. The hair on the chest has become white as well. The product has not been administered this year. The shampoo was changed to the one with rich moisture at the

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 115 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00122

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											time when the symptom of thinning of the hair throughout the body was observed, but it was ineffective. Therefore, the shampoo was changed back to the original. There was no abnormality in blood test, urinary test and fecal test. The product was given by a friend of the animal owner and the attending vet didn't prescribed the product to the dog.
05-Aug-2019	UAE; 19JP000145; Ehime; Japan	Species: Feline Breed: Feline various breeds Sex: U Sex qualifier: Unknown Age: 1.00 Month(s) Weight: 300 gms	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	05-Aug-2019	05-Aug-2019	0 Day(s)	D-B	As reported by the attending veterinarian, the cat (1-month-old, 300 g, gender unknown, intact, mixed breed cat) was brought to the hospital at around 10:00 am on 05 Aug 2019, and as flea infestation was observed, FRONTLINE SPRAY (Lot number: unknown, Expiry date: unknown, Topical, 1 mL/head) was administered by the attending veterinarian. Since the cat became recumbent and limp, it was brought back to the hospital at around 4:00 pm. The cat was hospitalized and an intravenous drip and heat retaining were given. The cat recovered on 09 Aug 2019. (The cat was rescued on 04 Aug 2019.)
07-Aug-2019	UAE; 19JP000152; -, Japan	Species: Canine Breed: Shetland Sheep Dog (Sheltie) Sex: M Sex qualifier: - Age: 1.00 Year(s) Weight: 9.8 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the attending veterinarian, the animal owner told the veterinarian that Frontline (Product: Unknown, Lot number and Expiry date: Unknown, Topical, Dose: Unknown) was administered to a 1 year old, 9.8 kg, male, intact sheltie and the dog vomited and developed diarrhea 30 minutes later. The date of administration is unknown.
20-Aug-2019	UAE; 19JP000162; -, Japan	Species: Feline Breed: Feline various breeds Sex: M Sex qualifier: Neutered Age: 13.00 Year(s) Weight: 5 kg	1	1	1	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	10-Aug-2019	10-Aug-2019	0 Day(s)	D-A	As reported by the attending veterinarian, on 10 Aug 2019, Frontline Plus Cat (Lot number and Expiry date: Unknown, Topical, 1 pipette) was prescribed and administered to a 13 year old, 5 kg, male, neutered mix cat at another animal hospital. The cat may have licked the application site. The cat subsequently developed loss of vigor, anorexia and tachypnea, and was crouching. The cat was brought to the hospital due to vomiting for 3 consecutive days. Although vomiting had stopped on the fourth day, the cat still had loss of vigor, anorexia and tachypnea. On 15 Aug 2019, a blood test and an X-ray examination were performed and treatment with drip infusion was given to the cat at another hospital. (It is unknown whether this was the hospital that had prescribed the product.) Although the white blood cell count was 19000 and the K level was a little low, there were no abnormalities. The X-ray also detected no abnormalities. On the next day, 16 Aug 2019, the cat was brought to the hospital. Body temperature was 36.2 degrees Celsius in the morning. The cat was breathing abdominally with his mouth open. Clouding of consciousness was observed and the condition deteriorated. At 5 PM, body temperature dropped to 33.6 degrees Celsius. At 6 PM, the cat vomited and died. Since the owner wrote in the medical questionnaire at the first visit that the cat was fed renal food, the cat may have had some kidney problems. The owner said that Frontline plus cat was administered as protection of Heartworm disease. Therefore, the product name is unsubstantiated.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 116 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00123

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
12-Sep-2019	UAE; 19JP000196; Osaka; Japan	Species: Canine Breed: Bichon Frise Sex: F Sex qualifier: Unknown Age: 11.70 Year(s) Weight: Unknown	1	1	1	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	08-Jul-2019	10-Jul-2019	2 Day(s)	D-A	As reported by the owner, on 08 Jul 2019, Frontline Plus (Lot number: unknown, Expiry date: unknown, Topical, dosage unknown) was administered to an 11 years and 8 months old, female, Bichon frise (BW: unknown, Reproductive status: unknown). The dog developed anorexia and loss of vigor two days later and was immediately brought to the hospital. According to the results of a blood test, an elevated level of hepatic function was observed. The dog had experienced elevated hepatic level several times before. Usually, the dog followed the course by displaying symptoms of vomiting at first, and then a treatment with intravenous drip and administration of drugs at the hospital was given for about 1 week and the symptoms resolved. However, the symptoms did not resolve this time and the dog died on 27 Aug 2019. The dog had a portosystemic shunt surgery at the age of 1 in the past. Although the dog developed transient convulsion after the surgery and was in a critical state, resolved recovery was achieved after a home care. Since the dog had good appetite and vigor prior to administration of Frontline Plus, the owner considers that the administration of Frontline Plus was a strain on the dog's liver and caused the death. UPDATE 16 Oct 2019: Following internal review, previously reported death was added to the VeDDRA coding.
17-Sep-2019	UAE; 19JP000198; Tokyo; Japan	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: F Sex qualifier: Neutered Age: 6.00 Year(s) Weight: 5 kg	1	1	1	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-Jun-2019*	14-Sep-2019	0 Day(s)	D-A	As reported by the attending veterinarian, in the morning on 14 Sep 2019, the animal hospital received a phone call from the animal owner. Frontline Plus Cat (Lot number and Expiry date: Unknown, Topical, 1 pipette) was administered to a 6 years old, 5 kg, female, spayed, Japanese cat by the owner. After about 1 hour, the cat collapsed and fell off the couch. After about 30 minutes, the cat was put in a carrier and was brought to the hospital. The director of the hospital examined the cat, and he thought that the carrier looked a little narrow and the airway was compressed. He saw the cat still breathing, but when he saw the animal again after a quick glance at a medical record, the animal was dead. The owner felt that the cat was not breathing on the way to the hospital from home. In spite of immediate cardiopulmonary resuscitation, intubation, intravenous administration of diluted Bosmin injection, etc. for an emergency, the cat died.
22-Jul-2019	UAE; 19MY000004; ; Malaysia	Species: Canine Breed: Medium crossbred (10 - 20 Kg) Sex: F Sex qualifier: Unknown Age: 2.50 Year(s) Weight: 14.9 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	18-Jul-2019*	20-Jul-2019	2 Day(s)	D-D	Suspected Lack of Efficacy claim: On 22 Jul 2019, the distributor reported the following for Boboy, a 2 year, 6 months old, 14.9 kg, intact female local cross dog. 18 Jul 2019: At 11:30 a.m., the veterinarian applied Frontline Combo Spot On M (10-20kg) (Batch S60309AL, expiry date: 01/2021), 1 tube topically to the skin between the scapulae, for deticking. It is unknown if this was the first dose. The dog was reported to be in good health at the time of the application, was not receiving any other products and had no recent procedures performed. 19 Jul 2019: 4:30 p.m., approximately 20-30% of ticks dropped off but were still alive, and the remaining 70-80% of the ticks were still on the body alive. 20 Jul 2019: 11:30 a.m., there were still 50% of the ticks remaining on the body. Some ticks were attached. 22 Jul 2019: The owner reported a suspected lack of efficacy. It is unknown if the event was treated.
16-Jul-2019	UAE;	Species: Canine	1	1	1	Product used:	N/A	2019*	N/A	D-A	As reported by pet owner via social media, 1 male dog, 6 years

N/A signifies the information for this field is either not available or not applicable

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

Report printed on 25-Oct-2019 at 8:39:59PM

*indicates Approximate date or weight

Page 117 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00124

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	19NL000127; -; Netherlands	Breed: - Sex: M Sex qualifier: Unknown Age: 6.00 Year(s) Weight: Unknown				FIPRONIL SPOT ON DOG Other products used: no other products Route: - Was the product used ok?: Unknown to Company					old, of unknown weight and unknown reproductive status received FRONTLINE of unknown lot and use by date, unsubstantiated which exact product or strength, by the dog's owner at unknown date. Dose and application frequency unknown. Owner reports that unknown time after application dog died. Unknown if veterinarian has been consulted. Owner reports that blood of the dog was sent to Utrecht and appears that the dog has died due to an unsubstantiated substance from FRONTLINE. Owner is grieving and unwilling to substantiate the information, provide additional information or laboratory/autopsy reports. Owner received the product from a pound where the dog used to be housed, they had surplus pipets, which the owner was instructed to use every 5 to 6 weeks.
16-Jul-2019	UAE; 19NL000129; -; Netherlands	Species: Canine Breed: Terrier (Jack Russell) Sex: F Sex qualifier: Unknown Age: 9.00 Year(s) Weight: 6 kg*	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	22-Mar-2015*	24-May-2015*	2 Day(s)	D-C	As reported by pet owner via social media, - 4 years ago - 5 year old under 6 KG female Jack Russel Terrier – Border Terrier mix dog of unknown reproductive status received FRONTLINE SPOT ON DOG S unknown expiry date and lot number from the owner 3 times 4 weeks apart 4 years ago starting in spring, 22mar2015 until 22may2015 approximately. Unknown time quickly after product administration the animal experienced skin rash, hair loss and a fever. The attending veterinarian practice is no longer in business. Thus no additional information can be obtained. The owner reports remembering that the veterinarian had hair, skin and blood analyzed and allegedly concluded an allergic reaction. The animal was treated with 1 unknown injection and unknown tablets taken daily for 1 week. The dog recovered from the fever 1 week after treatment started. The dog recovered from the skin rash and regained hair 4 weeks after initial symptoms were observed. Thus the dog fully recovered after 4 weeks.
29-Jul-2019	UAE; 19NL000131; -; Netherlands	Species: Canine Breed: Retriever (N. Scotia Duck Tolling) Sex: F Sex qualifier: Unknown Age: - Weight: 15 - 17 kg*	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	28-Apr-2019	01-Jul-2019	3 Day(s)	D-D	As reported by pet owner, female dog, Nova Scotia Duck Tolling Retriever unknown age weighing between 15 and 17 kilos of unknown reproductive status received FRONTLINE COMBO DOG M from the dog's owner 3 times 4 weeks apart. Last product application was approximately on 28-jun-2019. Prior to first treatment, unknown if fleas were present on the dog. Roughly 10 fleas were found on the dog after last treatment by the animal owner on 01-jul-2019. On 15-jul-2019 no more fleas were found on the dog. Unknown if the dog is housed with or has contact with other animals.
15-Jul-2019	UAE; 19NL000135; -; Netherlands	Species: Canine Breed: Pug Sex: M Sex qualifier: Unknown Age: 5.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	Jul-2019*	15-Jul-2019*	N/A	D-C	As reported by pet owner via social media, 5-year-old unknown weight male Pug dog of unknown reproductive status received FRONTLINE SPOT ON DOG S expiry date 02-2021 and lot number S20324AX from the owner at unreported date. Unknown time after product administration the animal experienced hot spots and a fever. The animal was treated with unknown injections of antibiotics for an unreported time by the attending veterinarian. Outcome of the reaction is not reported.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
 Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
 *indicates Approximate date or weight

Page 118 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00125

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
30-Jul-2019	UAE; 19NL000137; -, Netherlands	Species: Feline Breed: - Sex: M Sex qualifier: Neutered Age: 10.00 Year(s) Weight: 5 - 6 kg*	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	26-Jul-2019	27-Jul-2019	1 Day(s)	D-D	As reported by pet owner, male neutered cat, 10 years old weighing over 5 kilos received FRONTLINE SPOT ON CAT, from the cat's owner once on 26-jul-2019 in the neck between the shoulder blades. 1 day after product administration on 27-jul-2019 the animal experienced hair loss and redness at the application site. The animal was taken to a veterinarian, but was not treated. The reaction is ongoing at the time the event was reported on 01-aug-2019. The animal has been treated with a variety of anti parasitic agents such as Stronghold, Advantix and FRONTLINE in the past, without adverse events occurring.
19-Jul-2019	UAE; 19NL000139; -, Netherlands	Species: Feline Breed: European Sex: F Sex qualifier: - Age: 14.00 Year(s) Weight: 5 kg	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	30-Mar-2019	12-Jul-2019	20 Day(s)	D-D	As reported by pet owner, 4 cats, 2 male Siamese weighing 4 kilos 3 and 13 years old, 1 female Persian 4 years old weighing 5 kilos and 1 European weighing 5 kilos and 14 years old of unknown reproductive status received FRONTLINE SPOT ON CAT from the cat's owner 4 times with roughly 4 weeks in between. Latest product administration 22-jun-2019, the day before the owner went on holiday. There were no fleas on the cats prior to last treatment. The cats stayed at home and do not go outside. The cats are not kept or have contact with other animals. On 12-jul-2019, once back from holiday, the owner reports she found fleas on the cats. The owner treated the cats again with FRONTLINE SPOT ON CAT on 12-jul-2019. The owner still found fleas on the cats on 19-jul-2019, but reports much less fleas than earlier.
19-Jul-2019	UAE; 19NL000140; -, Netherlands	Species: Canine Breed: - Sex: F Sex qualifier: - Age: 7.00 Month(s) Weight: 7 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	N/A	22-Jun-2019*	1 Day(s)	D-D	As reported by pet owner, dogs, 16 years old 2 kilo male Chihuahua, 11 years old 7 kilo unknown mix female Boomer and 7 months old 7 kilo female mixed dog of unknown reproductive status received FRONTLINE COMBO DOG S from the dog's owner latest on 21-jun-2019 and 19-jul-2019, even though normally owner reports the dogs have been treated every 8 weeks for years. Unknown time after treatment on 21-jun-2019, fleas were suddenly observed on the dogs by the owner. Fleas are still found on the dogs after 19-jul-2019 treatment. It is unknown if the dogs are housed with other animals. Unknown if the dogs go outside. It is unknown if the dogs have contact with other animals. Dogs do not swim and are not washed prior to or after treatment.
24-Jul-2019	UAE; 19NL000141; -, Netherlands	Species: Feline Breed: European Sex: F Sex qualifier: Unknown Age: 13.00 Year(s) Weight: 3 kg	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Overdose)	02-Jul-2019	23-Jul-2019	0 Day(s)	D-D	As reported by pet owner, 2 European cats, 1 neutered male weighing 4.4 kilos 2 years old, 1 female 13 years old weighing 3 kilos of unknown reproductive status received FRONTLINE SPOT ON CAT from the cat's owner 2 times with 3 weeks in between, which is a too short period according to the label. First administration was on 02-jul-2019, latest product administration 23-jul-2019. There were fleas on the cats prior to first treatment, which is why the owner started the treatment. 3 weeks after first treatment, the owner reports she still found fleas on the cats. The owner treated the cats again with FRONTLINE SPOT ON CAT on 23-jul-2019. The cats are housed with 1 other unidentified animal of unknown flea treatment status. The cats go outside. It is unknown if the cats have contact with other animals.
04-Aug-2019	UAE; 19NL000142; -, Netherlands	Species: Feline Breed: British Shorthair	1	1	0	Product used: FIPRONIL 10%/S	12-Aug-2018	01-Jul-2019	N/A	D-D	As reported by pet owner, 2 British Shorthair cats, both male weighing 6 kilos, 3 and 10 years old of unknown reproductive status received FRONTLINE SPOT ON COMBO CAT from the

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 119 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00126

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex: M Sex qualifier: Unknown Age: 3.00 Year(s) Weight: 6 kg				METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company					cat's owner year round every 8-10 weeks, as flea control. The cat's owner noticed some fleas on the cats on 01-jul-2019 and administered FRONTLINE SPOT ON COMBO CAT as flea treatment, unknown time after previous product administration. 4 weeks after last administration the owner still observed fleas on the cats and administered FRONTLINE SPOT ON COMBO CAT again on 29-jul-2019. 04-aug-2019 the owner reports she found much fleas (3-6) fleas per cat. The cats are housed with fish. The cats go outside. The cats have contact with other animals whilst outside, where they are in contact with several other cats.
08-Aug-2019	UAE; 19NL000143; -; Netherlands	Species: Feline Breed: - Sex: U Sex qualifier: - Age: - Weight: 4 kg	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	25-Jul-2019	25-Jul-2019	0 Day(s)	D-D	As reported by pet owner, 4 cats, 2 weighing 4 and 2 weighing 5 kilos of unknown age, race, sex and of unknown reproductive status received FRONTLINE SPOT ON COMBO CAT, by the cat's owner once on 25-jul-2019. Unknown if there were fleas on the cats prior to treatment. After product administration, the owner reports she immediately found fleas on the cats. Cats were subsequently treated with Advantage, unknown outcome. Cats go outside. It is unknown if the cats have contact with other animals. It is unknown if the cats are kept with other animals.
08-Aug-2019	UAE; 19NL000145; -; Netherlands	Species: Canine Breed: - Sex: F Sex qualifier: Unknown Age: 11.00 Year(s) Weight: 5.5 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	22-Aug-2017	13-Jul-2019	0 Day(s)	D-D	As reported by pet owner, a 11 year old 5.5 kilo female Boomer dog received FRONTLINE SPOT ON DOG S batch number and expiry date unknown cutaneous between the shoulder blades by the dog owner for years with unknown frequency, latest administration was on 13-jul-2019. Unknown if before the last product application, there were fleas present on the dog. After product administration, the animal owner still experienced fleas on the dog. Dog was taken to a veterinarian and was subsequently treated with NEXGARD on 20-jul-2019. After NEXGARD treatment the owner reports the flea problem has decreased. It is unknown if the dog has contact with other animals. It is unknown if the dog is housed with other animals. It is unknown if the dog goes outside.
14-Aug-2019	UAE; 19NL000146; -; Netherlands	Species: Canine Breed: Pomeranian Sex: F Sex qualifier: - Age: 1.50 Year(s) Weight: 2 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	17-Jul-2019	24-Jul-2019	1 Week(s)	D-D	As reported by pet owner, 3 dogs, 8 and 6 year old male Chihuahuas weighing 2 and 3 kilos and a female Pomeranian approximately 1,5 years old weighing 2 kilos of unknown reproductive status received FRONTLINE COMBO DOG S from the dog's owner on 17-jul-2019. Prior to first treatment, fleas were present on the dogs. The owner reports fleas are still found on the dogs 1 week after treatment on 24-jul-2019. Unknown if the dogs go outside, have contact with other animals or are housed with other animals.
13-Aug-2019	UAE; 19NL000149; -; Netherlands	Species: Canine Breed: - Sex: M Sex qualifier: -	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products	N/A	13-Jul-2019*	N/A	D-D	As reported by pet owner, 1 male dog, unknown age and weight of unknown reproductive status received FRONTLINE unsubstantiated which product or strength, by the dog's owner at for over 12 years at unknown frequency, last product

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 120 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00127

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: - Weight: Unknown				used: no other products Route: - Was the product used ok?: Unknown to Company					administration date unknown. Animal owner reports fleas on the dog unknown time after last product application. Outcome of the reaction is not reported. It is unknown if the dog is housed with other animals. Unknown if the dog goes outside. It is unknown if the dog has contact with other animals.
16-Aug-2019	UAE; 19NL000150; -; Netherlands	Species: Canine Breed: Retriever Labrador Sex: F Sex qualifier: - Age: 3.00 Year(s) Weight: 25 - 30 kg*	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	N/A	09-Aug-2019*	N/A	D-D	As reported by pet owner, a 3 year old 25 - 30 kilo female Labrador Retriever dog of unknown reproductive status received FRONTLINE COMBO L batch number and expiry date unknown from the dog owner every 4 weeks for a couple of years. Exact latest product administration date unknown. After latest product administration, the animal owner experienced up to 30 fleas on the dog starting on 09-aug-2019 approximately, which the owner reports is roughly 1 week after latest application. The owner reports that the dog swims almost every day. The owner vacuums the house twice daily. It is unknown if the dog is housed with other animals. It is unknown if the dog has contact with other animals. Dog was subsequently treated with Bravecto, which the owner reports to work immediately. However, final outcome of the reaction is not reported.
12-Aug-2019	UAE; 19NL000151; -; Netherlands	Species: Feline Breed: European Sex: U Sex qualifier: - Age: 6.00 Month(s) Weight: 2 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	08-Aug-2019	12-Aug-2019	4 Day(s)	D-D	As reported by pet owner, 1 European cat, 5 – 6 months old weighing 2 kilos of unknown sex and reproductive status received FRONTLINE SPOT ON COMBO CAT, by the cat's owner once on 08-aug-2019. Fleas were present on the cats prior to treatment. After product administration, the owner reports he still found fleas on the cat on 12-aug-2019. Cat does not go outside. It is unknown if the cat is housed with other animals. It is unknown if the cat has contact with other animals.
19-Aug-2019	UAE; 19NL000152; -; Netherlands	Species: Canine Breed: Shih Tzu Sex: M Sex qualifier: - Age: 5.00 Year(s) Weight: 5 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Overdose)	01-May-2019*	31-Jul-2019*	20 Day(s)	D-D	As reported by pet owner, male Shih Tzu dog, 5 years old, weighing 5 kilos of unknown reproductive status received FRONTLINE SPOT ON DOG S batch number and expiry date unknown, by the dog's owner at unknown date and unknown frequency for the last 3 months, 3 weeks between latest 2 product administrations. Animal owner reports fleas on the dog after second to last product application unknown exact date and thus administered the product again after 3 weeks instead of the minimum period of 4 weeks according to the SPC, thus possibly overdosing the dog. The owner still reports fleas unknown time after last product administration. Dog has since received Credelio from the veterinarian. Outcome of the reaction is not reported. It is unknown if the dog is housed with other animals. Unknown if the dog goes outside. It is unknown if the dog has contact with other animals.
26-Aug-2019	UAE; 19NL000153; -; Netherlands	Species: Canine Breed: - Sex: M Sex qualifier: - Age: 4.00 Year(s)	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON	05-Aug-2019*	26-Aug-2019	3 Week(s)	D-D	As reported by pet owner, a 4 year old 9 kilo male Boomer Dog received FRONTLINE COMBO DOG S batch number and expiry date unknown cutaneous between the shoulder blades from the dog owner once on 05-aug-2019. Before application, the dog was itching often and the owner suspected fleas on the dog. 3 weeks

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 121 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00128

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: 9 kg				Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company					after product administration, 26-aug-2019, fleas were found on the dog by the attending veterinarian and dog was itching still. It is unknown if the dog goes outside or has contact with other animals. It is unknown if the dog is housed with other animals. Dog was treated with Vectra 3D against fleas and Prednisolone against itching, as prescribed by the veterinarian. Outcome of the reaction is unknown.
03-Sep-2019	UAE; 19NL000154; -, Netherlands	Species: Feline Breed: - Sex: M Sex qualifier: Neutered Age: - Weight: 7 kg	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	02-Sep-2019	03-Sep-2019	1 Day(s)	D-D	As reported by animal owner, male neutered crossbred cat, weighing 7 kilos of unknown age received FRONTLINE SPOT ON CAT, from the cat's owner once on 02-sep-2019 topically between the shoulder blades. The animal was treated because the owner found 1 tick on the cat a few days before administration. 1 day after product administration, on 03-sep-2019, the owner reports that the cat experienced hair loss at the application site. The reaction is ongoing at the time the event was followed up on 04-sep-2019.
22-Aug-2019	UAE; 19NL000155; -, Netherlands	Species: Canine Breed: - Sex: F Sex qualifier: Unknown Age: 7.00 Year(s) Weight: 6 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	N/A	22-Aug-2019*	1 Week(s)	D-D	As reported by pet owner, a 7 year old female dog weighing 6 kilo of unknown race and reproductive status received FRONTLINE COMBO DOG S batch number and expiry date unknown cutaneous between the shoulder blades from the dog owner for an extended period of time every 4 weeks, latest administration on 15-aug-2019. Unreported time after product administration owner found 6 ticks on the dog within an unknown report of time. It is unknown if the dog goes outside or has contact with other animals. It is unknown if the dog is housed with other animals.
19-Aug-2019	UAE; 19NL000156; -, Netherlands	Species: Canine Breed: - Sex: F Sex qualifier: Unknown Age: 7.00 Year(s) Weight: 6 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	N/A	18-Aug-2019*	N/A	D-D	As reported by pet owner, a 7 year old female dog weighing 6 kilo of unknown race and reproductive status received FRONTLINE COMBO DOG S expiry date nov-2019 and batch number unknown cutaneous between the shoulder blades from the dog owner for a period of many years every 5 to 6 weeks, latest administration date unknown. Unreported time after latest product administration owner found fleas on the dog. It is unknown if the dog goes outside or has contact with other animals. The dog is housed with a number of other animals of unknown flea treatment status. The dog is also housed with a bird which was never treated for fleas.
23-Aug-2019	UAE; 19NL000157; -, Netherlands	Species: Canine Breed: - Sex: F Sex qualifier: Unknown Age: 4.00 Year(s)	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: FIPRONIL SPOT ON DOG;	28-Jul-2019	23-Aug-2019	26 Day(s)	D-D	As reported by pet owner, 2 female dogs, 4 and 10 years old weighing 11-12 and 9.1 kilos respectively of unknown reproductive status received FRONTLINE SPOT ON DOG M and S respectively by the dogs owner on 28-jul-2019. Prior to first treatment, fleas were present on the dogs. Fleas are still found on the dogs on 23-aug-2019, 4 weeks after first treatment. Unknown if the dogs go

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 122 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00129

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: 11 - 12 kg				Route: Topical / Cutaneous Was the product used ok?: Unknown to Company					outside, have contact with other animals or are housed with other animals.
30-Aug-2019	UAE; 19NL000158; -; Netherlands	Species: Canine Breed: Retriever (Labrador, Yellow) Sex: M Sex qualifier: - Age: 7.00 Year(s) Weight: 31 - 35 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	22-Aug-2019	29-Aug-2019	1 Week(s)	D-D	As reported by pet owner, a 7 year old female Labrador dog weighing 31-35 kilos of unknown reproductive status received FRONTLINE COMBO DOG L expiry date and batch number unknown, cutaneous unreported site of administration from the dog's owner once on 22-aug-2019. Fleas were present on the dog prior to treatment. 7 days after product administration the owner still found fleas on the dog. It is unknown if the dog goes outside or has contact with other animals. It is unknown if the dog is housed with other animals. Dog was subsequently treated with unknown pill prescribed by the veterinarian. Outcome of the reaction is not reported.
05-Sep-2019	UAE; 19NL000161; -; Netherlands	Species: Feline Breed: European Sex: F Sex qualifier: - Age: 1.00 Year(s) Weight: 3 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	11-Jul-2019	08-Aug-2019	0 Day(s)	D-D	As reported by pet owner, 2 female European cats, weighing 3 and 4 kilos 1 and 7 years old of unknown reproductive status received FRONTLINE SPOT ON COMBO CAT from the cat's owner on 11-jul-2019 and 08-aug-2019, 4 weeks apart, topically between the shoulder blades. There were fleas on these recently adopted cats prior to first treatment, which is why the owner started the treatment. Approximately 4 weeks after first treatment, the owner reports she still found fleas on the cats. 05-sep-2019 the cats have been treated with Bravecto, after consultation with a veterinarian. Unknown if the cats go outside, have contact with other animals or are housed with other animals. Final outcome is not reported.
02-Sep-2019	UAE; 19NL000163; -; Netherlands	Species: Feline Breed: - Sex: U Sex qualifier: - Age: - Weight: Unknown	11	11	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	N/A	02-Sep-2019	N/A	D-D	As reported by pet owner, 11 cats, unknown age, sex and weight of unknown reproductive status received FRONTLINE SPOT ON CAT by the cat's owner at unknown date once in 2019. There were multiple fleas on the cats prior to first treatment. 1 week after product administration on 02-Sep-2019, the owner reports she still found fleas on the cats. It is unknown if the cats have contact with other animals or go outside. The cats are kept with 1 dog. Unknown if the dog is treated and or has contact with other animals.
09-Sep-2019	UAE; 19NL000171; -; Netherlands	Species: Feline Breed: European Sex: F Sex qualifier: - Age: 10.00 Year(s) Weight: 6 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products	12-Aug-2019*	02-Sep-2019*	0 Day(s)	D-D	As reported by pet owner, 2 European cats, 1 male weighing 4 kilos 15 years old, 1 female 10 years old weighing 6 kilos of unknown reproductive status received FRONTLINE COMBO CAT from the cat's owner 2 times with 3 weeks in between, which is a too short period according to the label. First administration was on 12-aug-2019, latest product administration 02-sep-2019. There were fleas on the cats prior to first treatment, which is why the owner started the treatment. 3 weeks after first treatment, the

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 123 of 867

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00130

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Route: Topical / Cutaneous Was the product used ok?: No (Overdose)					owner reports he still found fleas on the cats. The owner treated the cats again with FRONTLINECOMBO CAT on 02-sep-2019. 4 days later, on 06-sep-2019, the owner still found fleas on the cats and consulted a veterinarian who prescribed Bravecto Plus. The cats are housed with 1 dog who also suffered from a flea infection and was subsequently treated with unknown treatment. It is unknown if the cats go outside or have contact with other animals. Outcome of the reaction is not reported.
09-Sep-2019	UAE; 19NL000172; -, Netherlands	Species: Canine Breed: Boxer Sex: F Sex qualifier: - Age: 7.00 Year(s) Weight: 25 - 30 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Overdose)	12-Aug-2019*	02-Sep-2019*	0 Day(s)	D-D	As reported by pet owner, female Boxer dog, weighing 25 - 30 kilos 7 years old of unknown reproductive status received FRONTLINE COMBO DOG L from the dog's owner 2 times with 3 weeks in between, which is a too short period according to the label. First administration was on 12-aug-2019, latest product administration 02-sep-2019. There were fleas on the dog prior to first treatment, which is why the owner started the treatment. 3 weeks after first treatment, the owner reports he still found fleas on the dog. The owner treated the dog again with FRONTLINE COMBODOG L on 02-sep-2019. 4 days later, on 06-sep-2019, the owner still found fleas on the cats and consulted a veterinarian who prescribed Bravecto tablets. The dog is housed with 2 cats who also suffered from a flea infection and were subsequently treated. It is unknown if the dog goes outside or has contact with other animals. Outcome of the reaction is not reported.
04-Sep-2019	UAE; 19NL000173; -, Netherlands	Species: Feline Breed: - Sex: F Sex qualifier: Neutered Age: 1.50 Year(s) Weight: 4 kg	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	04-May-2018*	04-Aug-2019*	0 Day(s)	D-D	As reported by pet owner, 2 female neutered cats, weighing 4 kilos 1.5 years old received FRONTLINE COMBO CAT from the cat's owner monthly since she first got the cats, approximately 1 year and 3 months ago, last product administration was on 04-aug-2019. After last product administration the owner reports fleas on the cats, on 04-aug-2019. She consulted a veterinarian who prescribed Credelio tablets for the cats, which were administered on 29-aug-2019. Unspecified time after Credelio administration, the owner reports the flea problem was over. It is unknown if the cats go outside or have contact with other animals. It is unknown if the cats are kept with other animals.
17-Sep-2019	UAE; 19NL000175; -, Netherlands	Species: Canine Breed: Boxer Sex: F Sex qualifier: Unknown Age: 10.00 Year(s) Weight: 35 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	N/A	10-Sep-2019*	5 Week(s) 1 Day(s)	D-D	As reported by pet owner, a 10 year old female Boxer dog weighing 35 kilos of unknown reproductive status received FRONTLINE COMBO DOG L, batch number and expiry date unknown, cutaneous between the shoulder blades from the dog's owner for an unknown period of time with unknown frequency, latest product administration on 05-aug-2019. On approximately 10-sep-2019 the owner reports to have found 2 fleas on the dog. It is unknown if the dog goes outside or has contact with other animals. It is unknown if the dog is housed with other animals. Outcome of the reaction is not reported.
16-Sep-2019	UAE; 19NL000178; -, Netherlands	Species: Canine Breed: Retriever (Golden) Sex: M	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE	14-Sep-2019	14-Sep-2019	0 Day(s)	D-B	As reported by pet owner, 1 male 11-year-old Golden Retriever dog, unknown weight and of unknown reproductive status received FRONTLINE COMBO DOG unsubstantiated which strength, by the dog's owner once on 14-sep-2019. After product

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 124 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00131

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: - Age: 11.00 Year(s) Weight: Unknown				9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company					administration the animal experienced respiratory distress and panting on the day of product administration, 14-sep-2019. Analysis/tests were not reported to be performed. Unknown if the animal was examined by a veterinarian or treated. Animal owner refuses to provide additional diagnostic information, after repeated requests. Fleas were present on the dog before application of the unsubstantiated product. Animal owner reports she still found fleas on the dog 48 hours after product application. It is unknown if the dog is housed with other animals. Unknown if the dog goes outside. It is unknown if the dog has contact with other animals. Outcome of the reactions is not reported.
16-Sep-2019	UAE; 19NL000179; -, Netherlands	Species: Feline Breed: - Sex: U Sex qualifier: Unknown Age: 6.00 Month(s) Weight: Unknown	2	2	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	04-Sep-2019	16-Sep-2019	12 Day(s)	D-D	As reported by pet owner, 2 6-month-old cats, unknown sex, breed and weight received FRONTLINE SPRAY, unknown use and dose, from the cat's owner once on 04-sep-2019. Uncertain if there were fleas on the cats prior to treatment. After product administration, the owner reports she found fleas on the cats on 16-sep-2019. It is unknown if the cats go outside or have contact with other animals. It is unknown if the cats are kept with other animals. Reaction was not treated. Outcome of the reaction is not reported.
16-Sep-2019	UAE; 19NL000180; -, Netherlands	Species: Feline Breed: European Sex: U Sex qualifier: Unknown Age: 1.50 Year(s) Weight: 3 - 4 kg*	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	23-Jun-2019*	16-Sep-2019*	1 Day(s)	D-D	As reported by pet owner, 2 cats, 1.5 – 2 years old, weighing 3 and 4 kilos, unknown sex and of unknown reproductive status received FRONTLINE SPOT ON COMBO CAT, by the cat's owner cutaneous between the shoulder blades 3 times with 4 weeks in between. Latest product application was approximately on 15-sep-2019. There were up to 20 fleas on the cats prior to first treatment. After last product administration, the owner reports she still found fleas on the cats. Cats go outside. It is unknown if the cats have contact with other animals. The cats are not housed with other animals. Outcome of the reaction is not reported.
18-Sep-2019	UAE; 19NL000181; -, Netherlands	Species: Canine Breed: - Sex: U Sex qualifier: Unknown Age: 4.00 Year(s) Weight: 11 - 12 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Overdose)	14-Jul-2019*	26-Aug-2019	1 Day(s)	D-D	As reported by pet owner, a 4 year old dog weighing 11-12 kilos of unknown sex, race and reproductive status received FRONTLINE COMBO DOG M expiry date and batch number unknown cutaneous between the shoulder blades from the dog's owner 3 times for a period of 6 weeks every 3 weeks, latest product administration on 25-aug-2019. The dog was overdosed, as the minimal treatment frequency according to the label is 4 weeks. Fleas were present on the dog, prior to first treatment. After latest product administration owner still found fleas on the dog. It is unknown if the dog goes outside or has contact with other animals. The dog is housed with 4 cats with the same flea infestation. Dog was treated with Bravecto on approximately 18-sep-2019, as prescribed by the veterinarian. Owner reports the flea problem was over after this treatment.
18-Sep-2019	UAE; 19NL000182; -, Netherlands	Species: Feline Breed: European Sex: U Sex qualifier: - Age: 1.00 Year(s)	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other	14-Jul-2019*	26-Aug-2019	1 Day(s)	D-D	As reported by pet owner, 4 European cats, 2 cats between 14-16 weeks old of unknown weight, 1 cat 1-1.5 years old weighing 4 kilos and 1 cat 6 years old weighing 5 kilos, all of unknown sex and reproductive status received FRONTLINE SPOT ON CAT expiry date and batch number unknown cutaneous between the shoulder

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 125 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00132

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: 4 kg				products Route: Topical / Cutaneous Was the product used ok?: No (Overdose)					blades from the cat's owner 3 times for a period of 6 weeks every 3 weeks, latest product administration on 25-aug-2019. The cats were overdosed, as the minimal treatment frequency according to the label is 4 weeks. Fleas were present on the cats, prior to first treatment. After latest product administration owner still found fleas on the cats. It is unknown if the cats go outside or have contact with other animals. The cats are housed with 1 dog with the same flea infestation. The mature cats were treated with Vlo kill and Bolfo and the kittens were treated with Exil spray for Kittens on approximately 18-sep-2019, as prescribed by the veterinarian. Owner reports the flea problem was over after these treatments.
25-Sep-2019	UAE; 19NL000195; -, Netherlands	Species: Canine Breed: Bernese Mountain Dog Sex: M Sex qualifier: - Age: 8.00 Year(s) Weight: 70 kg*	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: - Was the product used ok?: No (Low dose)	Jul-2019*	Sep-2019*	0 Day(s)	D-D	Owner of 2 dogs and 2 cats, this case is related to the dogs. Both dogs 8 years, Newfoundland and Bernese mountain dog resp. 75 and 70 kg approx. Owner states that she treated the animals every month since april, FL combo alternating with Advantage. She states that fleas are present with FL Combo and not with Advantage. Dosing with XL pipette is no enough with these dogs, and she states adding half a FL combo M dosage, while she should add a whole FL combo M dosage with the XL dose. Story of owner varies during conversation. The cats in the household are also treated against fleas, they also do go out and about.
25-Sep-2019	UAE; 19NL000196; -, Netherlands	Species: Feline Breed: European Sex: U Sex qualifier: - Age: 2.00 Year(s) Weight: 5 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: - Was the product used ok?: Unknown to Company	Jul-2019*	Sep-2019	0 Day(s)	D-D	Owner of 2 dogs and 2 cats, this case is related to the dogs. Both dogs 8 years, Newfoundland and Bernese mountain dog resp. 75 and 70 kg approx. Owner states that she treated the animals every month since april, FL combo alternating with Advantage. She states that fleas are present with FL Combo and not with Advantage. Dosing with XL pipette is no enough with these dogs, and she states adding half a FL combo M dosage, while she should add a whole FL combo M dosage with the XL dose. Story of owner varies during conversation. The cats in the household are also treated against fleas, they also do go out and about.
26-Sep-2019	UAE; 19NL000198; -, Netherlands	Species: Canine Breed: Small crossbred (<10 Kg) Sex: F Sex qualifier: Neutered Age: 6.00 Year(s) Weight: 8 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	N/A	26-Aug-2019*	N/A	D-D	As reported by pet owner, a 6 year old female neutered crossbred dog weighing 8 kilos received FRONTLINE SPOT ON DOG S expiry date and batch number unknown cutaneous in the neck from the dog owner at least 3 times with unknown frequency, latest administration date 14-sep-2019. Unreported time after latest product administration owner found fleas on the dog. It is unknown if the dog goes outside or has contact with other animals. Unknown if the dog is housed with other animals. Attending veterinarian prescribed Vectra 3D, which was administered on 24-sep-2019. The owner reports the flea problem got better.
17-Jul-2019	UAE; 19NO000050; Østfold; Norway	Species: Feline Breed: Maine Coon Cat Sex: M Sex qualifier: - Age: 14.40 Year(s)	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products	2018*	2018	N/A	D-D	The cat received Frontline "a while ago" (as stated in the report - not further specified). The cat developed pruritus at the application site and further cranially, as well as periorcular pruritus. No further information is given in the report. 22 JUL 2019 MAH comment: Animal details: Maine Coon cat, male, intact, 14.4 years, 6.1 kg taken from patient screen. Product unsubstantiated entered as

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 126 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00133

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: 6.1 kg				Route: Topical / Cutaneous Was the product used ok?: Unknown to Company					FRONTLINE SPOT-ON for cats.
27-Aug-2019	UAE; 19NZ000180; -; New Zealand	Species: Canine Breed: Canine various breeds Sex: M Sex qualifier: Neutered Age: 2.00 Year(s) Weight: 22 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Intentional)	21-Jul-2019	21-Jul-2019*	N/A	D-D	As reported to me by the owner, she treated Trust, a 22kg , 2 year old, male neutered crossbreed dog with Frontline Plus for Large dogs, batch S63102AX, expiry 09/2021 three times in the past 5 weeks because fleas were seen on the dog. The most recent treatment was 26 Aug 2019 and prior to this on approximately 11 Aug and 21 July. There is a cat in the household and the owner says she routinely treats both her cat and dog monthly with the appropriate Frontline Plus product and there have been no problems until this last month. She is seeing approximately 2-3 fleas every few days on the dog but none on the cat. There is no change in the dog's environment or activity but it is walked daily including in a park.
02-Sep-2019	UAE; 19NZ000181; -; New Zealand	Species: Canine Breed: Bichon Frise Sex: M Sex qualifier: Unknown Age: Unknown Weight: 5.7 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	05-Aug-2019*	05-Aug-2019	0 Day(s)	D-D	As reported to me by the owner, approximately four weeks ago (5 August 2019) he treated his male neutered, 5.75kg Bichon Papillon cross dog with Frontline Plus for small dogs (FLP), batch and expiry unknown but during the past 2-3 weeks he has found fleas on his dog. He said he regularly treats his dog with FLP but was unable to provide treatment dates. There is only one dog in household, no cats and no change in environment or activity.
06-Sep-2019	UAE; 19NZ000182; -; New Zealand	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: F Sex qualifier: Neutered Age: 7.00 Year(s) Weight: 3.8 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	31-Jul-2019*	21-Aug-2019	0 Day(s)	D-D	As reported by the owner, FRONTLINE PLUS for cats, batch S40716EW, exp 05 2021, was applied to a 7 year old domestic short hair female 3.8 kg cat called Gina, on approximately 31 July 2019 then repeated on 21 Aug 2019. The owner noted one flea on herself three weeks after the application on 31 July 2019, and had noted one flea on the day of reporting (4 Sept 2019). She is unsure if there are more fleas on the cat, but has noticed the cat scratching occasionally. She reports she treats the cat monthly with Frontline Plus. She has no other pets. The cat has outdoor access.
10-Sep-2019	UAE; 19NZ000188; -; New Zealand	Species: Feline Breed: Feline Other Sex: M Sex qualifier: Neutered Age: 15.00 Year(s) Weight: 5.1 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical /	10-Jun-2019*	10-Jun-2019*	N/A	D-D	As reported by the owner, FRONTLINE PLUS for cats, batch and expiry unknown, was applied to a 15 year old male neutered 5.1kg Mandalay breed male neutered cat for approximately three months (estimated start date of 10 Jun 2019) for flea and tick treatment. The owner noticed the experienced some hair loss over its legs and chewing at its fur recently, and her veterinarian thought this was due to fleas, although no fleas were found on examination. The owner has noticed the cat is scratching occasionally. She had previously used Bravecto and Advantage.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 127 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00134

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Cutaneous Was the product used ok?: Unknown to Company					
19-Sep-2019	UAE; 19NZ000198; -; New Zealand	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: F Sex qualifier: Neutered Age: 2.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	15-Sep-2019	19-Sep-2019	4 Day(s)	D-D	As reported to me by the owner, every four weeks she applies Frontline Spray to her 2 year old, weight unknown, female spayed, DSH cat called Subi. The most recent treatment was 15 Sept 2019 using 100mL, batch SO2002A, expiry 8/2020. The owner complained that four days after application she found three fleas on her cat. She sprays and rubs the product into the fur but does not count the number of pumps applied. The owner releases a flea bomb in the house twice yearly, dates and product unknown and before now has not had any flea problems. There is no one in the household getting bitten.
20-Sep-2019	UAE; 19NZ000199; -; New Zealand	Species: Feline Breed: - Sex: U Sex qualifier: Unknown Age: Unknown Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	16-Jul-2019	10-Sep-2019	8 Week(s)	D-D	As reported to me, the owner regularly treats her two cats, details unknown, with FRONTLINE PLUS for Cats (FLP) and her family was getting bitten inside the house by fleas and on 10 Sept 2019 she applied Advantage to the cats and said the problem gradually resolved over the next ten days. She was phoning to complain about the product. When requested specific treatment dates the owner checked her calendar and the last two treatments with Frontline Plus were 28 May 2019 and 16 July 2019. The recent treatment with FLP was batch S40307, expiry 01/2021. Application technique was queried and appears correct. The gap between the most recent FLP treatment and the previous one is 7 weeks, longer than recommended, and the gap between the last FLP treatment and the complaints of infestation was 8 weeks.
23-Sep-2019	UAE; 19NZ000202; -; New Zealand	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	02-Sep-2019*	02-Sep-2019*	0 Day(s)	D-D	As reported by the owner, FRONTLINE PLUS for cats, batch S40716BW, exp 05 2021, was applied to a cat by the owner on approx. 2 Sep 2019. The owner was still seeing around 4 fleas on the cat, so re applied the dose on 22 Sep 2019. She had not previously flea treated for an extended period of time. She had found one flea when combing the cat on 22 Sep 2019. She had previously used Advantage flea treatment and was seeing live fleas on the cat when treating with this product also.
01-Aug-2019	UAE; 19PH000012; -; Philippines	Species: Canine Breed: - Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: Frontline (Non-specific) Other products used: no other products Route: unknown	12-Jul-2019*	18-Jul-2019*	6 Day(s)	D-D	Suspected Lack of Efficacy: On 1 Aug 2019, the pet owner reported via email the following event for an unknown number of dogs, no other signalment was provided. Owner applied frontline(unsustantiated) 2 weeks ago and observed enormous ticks and fleas on dogs. Event start date below is only approximate.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 128 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00135

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Was the product used ok?: Unknown to Company					
22-Jul-2019	UAE; 19PL000022; -; Poland	Species: Canine Breed: German Shepherd Dog Sex: U Sex qualifier: Unknown Age: 8.00 Week(s) Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: SC-subcutaneous Was the product used ok?: No (Route not indicated / recommended)	22-Jul-2019*	22-Jul-2019*	0 Day(s)	D-C	Suspected adverse event: as reported by attending veterinarian, canine, 8 weeks old German Shepherd Dog (other signalment unknown) received FRONTLINE range product (FRONTLINE SPOT ON DOG L placed by default, since DVM doesn't know the exact product, dose is unknown). Product was administered subcutaneously with a syringe with a needle, which was provided by owner of dog's breeding, by animal owner on an unknown date (22 JUL 2019 placed by default). At an unknown time after product administration (22 JUL 2019 placed by default as start date of the event) the animal experienced hives (urticaria) The animal is currently treated with i.v. in the reporter clinic. The attending veterinarian's level of suspicion is: high.
09-Sep-2019	UAE; 19RO000010; -; Romania	Species: Canine Breed: Maltese Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	01-Aug-2019*	07-Aug-2019*	0 Day(s)	D-D	LACK OF EXPECTED EFFICACY: as reported by the animal owner, a male DOG (breed Maltese, weight unknown, health conditions unknown) was treated by the animal owner with the product FRONTLINE COMBO (bath number unknown, expiry date unknown, dose unknown, route unknown). But since the last application in AUG 2019, especific date unknown, (01 AUG 2019 choosen by default) in less than a week later (07 AUG 2019 choosen by default), she observed fleas on her dog. She has been waiting another three weeks (carring for him with fleas baths and flea a combo, 01 SEP 2019 was chosen by default) and then she administered a dose of FRONTLINE COMBO (dose and date of administration is unknown) hoping that it was just bad luck than the first dose had no effect at all. The result was the same, even worse. Four days after the application (date unknown) she observed fleas again. Outcome to date is unknown. No veterinarian was involved in the case. The owner bought each time 6 pipettes for six months, and she used for over the year. In AUG 2019 (date is unknown), the onwner bought 6 pipettes again. Until now did not have any problems.This is the extent of the information available.
09-Jul-2019	UAE; 19RU000021; -; Russia	Species: Canine Breed: - Sex: F Sex qualifier: Unknown Age: 13.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Indication not indicated / recommended)	03-Jul-2019	04-Jul-2019*	1 Day(s)	D-D	Suspected lack of efficacy: as reported by the owner, the dog (13 years, female) and another dog (other signalment unknown) and 1 kitten in house, in unknown health state received Frontline Spray (lot S03002A, 11-2021, topical) administered by owner on 03 JUL 2019. Frontline Spray was bought in veterinary clinic in spring. The kitten was found on street and move to house by the owner. The kitten had fleas and was placed in tambour, dogs were in room (case linked to case nr 19RU000022 – cat brought to the same household). The owner treated her own dogs to prevention of fleas infestation and the kitten to kill fleas. After treatment, fleas didnt die (04 JUL 2019 entered by default as start of reaction), there were no outcome of using the product (previously, when the owner had treated her animals by Frontline Spray, fleas died, not tried to turn back upon animals. Also the owner sprayed the room, tambour, and bedding with Frontline Spray. Despite all precaution the dogs in house were infested by fleas. According to owner report, Frontline Spray (bought in spring) had different structure after drying on fur, different from structure after using FRT Spray ,

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 129 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that out product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00136

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											which had bought previous times. 05-AUG-19 QA results received: Investigation completed for FIPRONIL SPRAY Lot# S03002A, expiry 2021-11-01. Case investigated by France - Toulouse. Final complaint evaluation A product quality complaint for FRONTLINE SPRAY, batch S03002A, was received by BIAH QA on the 16th of July 2019. The complaint description is "lack of efficacy". This is the first complaint for this batch. The complaint sample is not received. The retention sample is conform but will not respond to a lack of efficacy. Batch record review: S003. Manufacturing date: 23/01/2018. Expiry date: NA. Manufacturing quantity: 8497 liters. Associated deviation(s): No deviation associated to this batch. Change control associated: This batch was not concerned by any change control. Observation(s): No observation associated
09-Jul-2019	UAE; 19RU000022; -, Russia	Species: Feline Breed: Feline Other: Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Indication not indicated / recommended)	03-Jul-2019	04-Jul-2019*	1 Day(s)	D-D	Suspected lack of efficacy: as reported by the owner, the feline, kitten (other signalment unknown) in unknown health state received Frontline Spray (lot S03002A, 11-2021, topical) administered by owner on 03 JUL 2019. Frontline Spray was bought in veterinary clinic in spring. The kitten was found on street and move to house by the owner. The kitten had fleas and was placed in tambour, dogs were in room (case linked to case nr 19RU000021 – dogs from the same household). The owner treated kitten to kill fleas and dogs to prevention of fleas infestation. After treatment, fleas didn't die (04 JUL 2019 entered by default as start of reaction), there were no outcome of using the product (previously, when the owner had treated her animals by Frontline Spray, fleas died, not tried to turn back upon animals. Also the owner sprayed the room, tambour, and bedding with Frontline Spray. Despite all precaution the dogs in house were infested by fleas. According to owner report, Frontline Spray (bought in spring) had different structure after drying on fur, different from structure after using FRT Spray, which had bought previous times.
26-Jul-2019	UAE; 19RU000027; -, Russia	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	23-Jul-2019*	24-Jul-2019*	1 Day(s)	D-D	Suspected adverse event: as reported by distributor, the dog (sex, weight, age are unknown) in unknown health state received Frontline Spray (lot S00415A, expiry date JAN 2021, 31 JAN 2021 entered by default, topical) administered by owner in JUL 2019 (date 23 JUL 2019 placed by default). Frontline Spray was bought in MARCH 2019. The product was applied during last 12 years with no adverse events caused, but usually Frontline Spray was bought in 100 ml presentation. It was the first time when owners bought 250 ml bottle. At an unknown time after application (24 JUL 2019 entered by default) the dog came out in spots (coded as generalised red spots), started itching and tearing out hair (coded as localised hair loss), got skin ulcers. The owner are suspicious if quality of the product is within normal limits.
07-Jul-2019	UAE; 19SE000119; -, Sweden	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: F Sex qualifier: Neutered Age: 1.00 Year(s) Weight: 4.2 kg	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used	01-Apr-2019*	07-Apr-2019*	N/A	D-D	As reported by the animal owner, an approx. 1-year old female neutered domestic shorthair cat, bodyweight 4.2 kg, in good health at the time of treatment, received FRONTLINE VET FOR CATS 100 MG/ML spot-on (batch S20702AW, EXP APR 2021, valid) 1 dose every 4 weeks on the neck administered by the animal owner since APR-2019. The owner reported that at first the cat came home with ticks (date not specified), in JUN-2019 the cat came home with lice and fleas for one week, the next week it had ticks again. The cat had been treated with FRONTLINE last year (2018, time period not further specified) with good effect.

N/A signifies the information for this field is either not available or not applicable

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

Report printed on 25-Oct-2019 at 8:39:59PM

*indicates Approximate date or weight

Page 130 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00137

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
18-Jul-2019	UAE; 19SE000122; -, Sweden	Species: Canine Breed: Dachshund (Miniature) Sex: F Sex qualifier: Pregnant Age: 6.00 Year(s) Weight: 6 kg	1	1	0	ok?: Yes Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Indication not indicated / recommended)	06-May-2019	05-Jun-2019*	N/A	D-B	As reported by the animal owner, a dog, female, pregnant (rough coated miniature dachshund, 6 kg, date of birth 18 JUN 2012, healthy) received FRONTLINE VET SPOT-ON FOR DOGS up to 10 kg (size S) (LOT S20901AX, EXP JUN 2021, valid) topically applied to the area between the shoulder blades, 1 dose given by the owner every 4 weeks on 06 MAY 2019, 03 JUN 2019 and 01 JUL 2019, as treatment against dandruff mites (off-label use, not listed in the local labelling). The owner described that the dog had a bleeding approximately at the same time as product administration or a few days later (not specified after which of the product administrations). The reaction was not treated. The dog was mated on 12 MAY 2019 and gave birth to two pups on 14 JUL 2019. According to the owner both pups were malformed with, among other things, missing ears (not further specified), and had to be euthanised (date not specified). The owner states that no veterinarian has been involved. No information available on the relatedness and inbreeding of this specific mating. UPDATE 5-AUG-2019: As reported by the owner, the bitch had had three litters prior to this one. The owner had used FRONTLINE in the kennel before and also on this bitch. The puppies were born without open ear canal and missing ears, they also had cleft palate and cleft nose. The owner reported this was the first time in 30 years she had seen malformed puppies. MAH added Veddra-code vaginal bleeding, and as AE was reported in both mother and offspring, the structural fields on the patient screen refers to the mother, while the Veddra-codes refers to both mother and offspring. UPDATE 27-AUG-2019 by MAH: Mother / offspring SAE case split in two cases according to new guidance. The mother will be reported in the case 19SE000122 and the offspring will be reported in the case 19SE000162. The cases are linked in the MAH database. Veddra-codes have been updated to reflect this case is only AE in mother.
18-Jul-2019	UAE; 19SE000124; -, Sweden	Species: Feline Breed: Domestic Mediumhair (Crossbred) Sex: F Sex qualifier: Neutered Age: 6.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: No (Treatment / vaccination program not respected)	2019*	2019*	N/A	D-D	As reported by the animal owner, a cat, female, neutered, 6 years old, healthy domestic cat (weight unknown) received FRONTLINE VET spot-on 1 dose (amount unknown) administered since the cat was 5 years old, administered by the owner every 3 weeks. After product administration (not further specified) the owner experienced lack of efficacy (not further specified). The product has been used more frequently than recommended (recommended every 4 weeks). MAH comment: the start date of the reaction has not been specified by the reporter, however has been estimated by the MAH due to submission purpose. UPDATE 19-AUG-2019: MAH revision of case, product in structured field corrected to FRONTLINE VET FOR CATS 100 MG/ML. Actual dose start date amended to '2019'.
18-Jul-2019	UAE; 19SE000125; -, Sweden	Species: Canine Breed: Retriever (Flat-Coat) Sex: M Sex qualifier: - Age: 4.00 Year(s) Weight: 29.000 - 32 kg	2	2	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the	2019*	2019*	N/A	D-D	A brief report concerning suspected lack of efficacy. As reported by an animal owner, two dogs, flatcoated retrievers, male, intact (4 years old, body weight 29 kg and 32 kg) received FRONTLINE VET SPOT-ON 100 MG/ML (size L) (LOT S20801AR, EXP MAY 2020, valid) on unknown date (MAH added 2019) by unknown route and unknown dose. Some time after product administration (not specified) the owner perceived lack of efficacy (not further specified). The MAH had contacted the reporter for additional

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 131 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00138

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						product used ok?: Unknown to Company					information but no more information was available at the time of reporting.
19-Jul-2019	UAE; 19SE000126; -, Sweden	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: 7.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	14-Jun-2019	Jul-2019*	unknown	D-D	A brief report concerning suspected lack of efficacy. As reported by the animal owner, a dog, 7 years old (born 2012), healthy, (breed, gender and weight unknown) received FRONTLINE VET SPOT-ON 100 MG/ML (size S) (LOT unknown) administered by the animal owner on 14 JUN 2019 and 01 JUL 2019. After product administration the owner perceived lack of efficacy (not further specified). The dog has no prior history of reaction to veterinary medicinal products.
18-Jul-2019	UAE; 19SE000127; -, Sweden	Species: Canine Breed: Belgian Tervueren Sex: M Sex qualifier: - Age: 6.00 Year(s) Weight: 20 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	2019	2019*	N/A	D-D	A brief report concerning lack of efficacy. As reported by the animal owner, a healthy 6-year old male intact Tervuren dog, body weight 20 kg, received FRONTLINE VET SPOT-ON for 20 kg (MAH estimated >10-20 kg size M, 1.34 ml) (batch unknown), by unknown route and unknown dose, administered by the owner every 3-4 weeks continuously throughout the year. After product administration (time not specified) the owner perceived lack of efficacy (not further specified).
22-Jul-2019	UAE; 19SE000128; -, Sweden	Species: Canine Breed: Canine (unknown) Sex: F Sex qualifier: Unknown Age: 8.00 Week(s) Weight: 7 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-Jul-2019	02-Jul-2019*	1 Day(s)	D-D	As reported by the animal owner, a dog, female, intact, 8 weeks (healthy, approx 7 kg, breed unknown) received FRONTLINE VET SPOT-ON (size S) (batch T20308AL, EXP DEC 2021, valid) administered by the animal owner on 01 JUL 2019. After product administration (not further specified) the owner found ticks on the dog almost every day, especially in the head region. Approx. one week after administration the dog showed signs of anorexia, although the owner was not sure this was related to the product administration. MAH comment: This case is classified as both 'SLEE' and 'Adverse reaction', but due to a limitation of the database it might be that only the highest hierarchical product problem type, which is 'Adverse reaction', has been transmitted.
19-Jul-2019	UAE; 19SE000129; -, Sweden	Species: Canine Breed: Shetland Sheep Dog (Sheltie) Sex: M Sex qualifier: - Age: 14.00 Month(s) Weight: 9 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	29-May-2019	05-Jul-2019	3 Day(s)	D-D	As reported by the animal owner, a dog, Shetland Sheepdog, male, intact (14 months, 9 kg) received FRONTLINE VET SPOT-ON FOR DOGS (size S for <10 kg; batch T20308AL, EXP DEC 2021, valid) according to weight administered by the owner on 29 MAY 2019 and again on 02 JUL 2019. On 05 JUL 2019 the dog was brought to a summer house area after which the owner observed ticks on the dog almost every day. The majority of the ticks were crawling around in the fur, while a few had attached. The dog was at good health at the time of treatment and had no prior history of reaction to veterinary medicinal products.
23-Jul-2019	UAE; 19SE000131; -, Sweden	Species: Canine Breed: - Sex: U Sex qualifier: Unknown Age: -	2	2	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products	2015*	2015*	0 Day(s)	D-D	A brief SLEE report. As reported by an animal owner, 2 dogs and 4 cats of unknown breed, body weight 2-12 kg, age 3-10 years old, gender not specified but the dogs were intact and the cats were neutered, received FRONTLINE VET SPOT-ON (for dogs and cats respectively) according to weight and label, administered by the owner 4-5 years ago (not further specified-set to approx. 2015).

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 132 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00139

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: Unknown				Route: Topical / Cutaneous Was the product used ok?: Unknown to Company					After product administration, the owner experienced problems with lack of efficacy (not further specified). The reporter did not want to give more information. The report has been split in two cases (one with the dogs and one with the cats) and the cases have been linked in the database, case numbers 19SE0000131 (dogs) and 19SE000132 (cats). UPDATE 27-AUG-2019: MAH reviewed case, deleted age and weight intervals in structural fields as the values are both for the dogs and the cats. Breed field (Canine unknown) deleted as agreed with NCA.
23-Jul-2019	UAE; 19SE000132; -, Sweden	Species: Feline Breed: - Sex: U Sex qualifier: Neutered Age: - Weight: Unknown	4	4	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	2015*	2015*	0 Day(s)	D-D	A brief SLEE report. As reported by an animal owner, 2 dogs and 4 cats of unknown breed, body weight 2-12 kg, age 3-10 years old, gender not specified but the dogs were intact and the cats were neutered, received FRONTLINE VET SPOT-ON (for dogs and cats respectively) according to weight and label, administered by the owner 4-5 years ago (not further specified-set to approx. 2015). After product administration, the owner experienced problems with lack of efficacy (not further specified). The reporter did not want to give more information. The report has been split in two cases (one with the dogs and one with the cats) and the cases have been linked in the database, case numbers 19SE0000131 (dogs) and 19SE000132 (cats). UPDATE 27-AUG-2019: MAH reviewed case, deleted age and weight intervals in structural fields as the values are both for the dogs and the cats. Breed field (Feline unknown) deleted as agreed with NCA.
24-Jul-2019	UAE; 19SE000134; -, Sweden	Species: Canine Breed: Canine Other Sex: M Sex qualifier: - Age: 8.00 Month(s) Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	2019*	2019*	N/A	D-D	As reported by an animal owner, a healthy 8-months old male intact Kromfohrlander (body weight unknown) received FRONTLINE VET SPOT-ON 100 MG/ML FOR DOGS 10-20 KG (size M) (batch S20625AX, exp. 31 MAR 2021, valid) 1 dose every 4 weeks, 5 doses in total, administered by the owner on unknown dates in 2019. After product administration (not further specified) the owner found ticks on the dog. Many of the ticks were dead, but were still attached to the skin. The owner observed that approx 5 ticks attached to the dog every day. The dog had not previously been treated with other medication.
26-Jul-2019	UAE; 19SE000136; -, Sweden	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: M Sex qualifier: Neutered Age: 7.00 Year(s) Weight: 6.3 kg	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	15-Feb-2019	15-Feb-2019*	0 Day(s)	D-D	An adverse event report from a veterinarian received by the MPA on April 12, 2019, regarding a cat, Domestic short hair, neutered male, 7 years old and bodyweight 6.3 kg. On February 15, 2019, the cat was treated topically with Frontline vet 100 mg/ml spot-on solution, batch no. unknown, 1 dose given, for ectoparasite prophylaxis. The owner reported that the cat lost fur at the application site. No itching was observed. The skin was mildly reddened at the site of local alopecia. According to the report, the symptoms resolved by April 12, 2019.
27-Jul-2019	UAE; 19SE000137; -, Sweden	Species: Canine Breed: Small crossbred (<10 Kg) Sex: M Sex qualifier: - Age: 8.00 Year(s) Weight: 7 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown	2019*	2019*	N/A	D-D	As reported by an animal owner, an 8-year old small crossbred dog (Lhasa apso/Shih tzu), male, approx 7 kg, healthy, received FRONTLINE COMP 2-10 KG (size S) (batch S62716AW, EXP SEP 2021, valid), 1 dose every 4 weeks administered by the owner during 2019 (dates not specified). After product administration (not further specified) the owner found attached ticks every day which sucked blood without dying. The dog had no prior history of reactions to any medicinal products.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 133 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00140

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Was the product used ok?: Unknown to Company					
17-Jul-2019	UAE; 19SE000153; -, Sweden	Species: Canine Breed: Canine Other Sex: F Sex qualifier: Unknown Age: 13.00 Year(s) Weight: 11 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	10-Jul-2019*	17-Jul-2019*	1 Week(s)	D-D	As reported by a pharmacist (first contact) and an animal owner (primary reporter), a 13-year old female Swedish Vallhund (Vastgotaspets), body weight 11 kg, received FRONTLINE VET 100 MG/ML (size M for >10-20 kg bw; batch: R21816AX, exp. NOV-2020) 1 dose topically on the skin between the shoulderblades administered by the owner on 10-JUL-2019 for tick control. Approximately 1 week later the owner removed approx. 20 attached ticks. The owner had used FRONTLINE for several years with satisfactory effect. FRONTLINE was only administered when there were ticks and every 6-8 weeks. The owner reported that treatment with FRONTLINE started in the spring 2019 but had a break when the weather was colder, then given again in the summer. In 2019 the dog had received three doses in total.
04-Aug-2019	UAE; 19SE000158; -, Sweden	Species: Canine Breed: Large crossbred (>20 Kg) Sex: F Sex qualifier: Neutered Age: 10.50 Year(s) Weight: 32 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: FIROCOXIB 227 MG CHEWABLE; Route: Topical / Cutaneous Was the product used ok?: Yes	02-Jun-2019	Jul-2019*	N/A	D-D	As reported by the daughter of the animal owner, a 10.5-year old female neutered crossbred dog (labrador/ samojed/ border collie/ golden retriever/ White Swiss Shepherd) body weight 32 kg, of fair condition (had a hormonal disruption condition causing bilateral alopecia in some spots) received FRONTLINE VET SPOT-ON FOR DOGS 20-40 KG (size L, batch: S20801AR, exp. MAY-2021) 1 dose every 4 weeks topically in the neck administered by unknown, first dose given 2-JUN-2019. The owner stated that approx. 100 ticks had been seen this summer despite treatment with FRONTLINE. Last year (2018) the dog received Scalibor but experienced wounds from the collar, Scalibor was replaced with FRONTLINE and it was working well. Two years ago (2017) the dog received Bravecto and experienced lack of efficacy. The dog had arthrosis and was also treated with Previcox 227 mg 0.5 tablet SID and a joint health product with greenlipped mussel extract (1 tabl SID).
05-Aug-2019	UAE; 19SE000159; -, Sweden	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: 8.00 Year(s) Weight: 5 kg	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	Mar-2015*	2015*	0 Day(s)	D-D	As reported by an animal owner, an approx. 8-year old cat (breed and gender unknown, body weight approx. 5 kg, healthy) received received FRONTLINE VET 100 MG/ML SPOT-ON FOR CATS unknown dose every 3 weeks, by unknown route from spring to autumn (MAH estimated from MAR-OCT 2015), subsequently the cat experienced lethargy. The time of onset was not specified but according to the owner the reaction occurred every time it received FRONTLINE. The cat had received FRONTLINE between 5 and 7 or 8 years of age. Treatment with FRONTLINE discontinued due to the reaction. At the time of the report the cat was 12 years old.
06-Aug-2019	UAE; 19SE000161; -, Sweden	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: M Sex qualifier: Neutered Age: 2.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	05-Jul-2019	05-Jul-2019	N/A	D-D	As reported by an animal owner, a 2-year old male neutered domestic cat (weight unknown) received FRONTLINE VET 100 MG/ML SPOT ON FOR CATS (batch S21808AX, exp. 11-2021) 1 dose applied topically in the neck by animal owner on the 5-JUL-2019 and 4-AUG-2019 for tick prevention. In conjunction with product administration the cat became like frozen (MAH veddra-coded 'Discomfort NOS') and went to rest for 1-2 hours. The cat experience the same reaction last year (2018) when treated with FRONTLINE.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 134 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00141

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
27-Aug-2019	UAE; 19SE000162; -, Sweden	Species: Canine Breed: Dachshund (Miniature) Sex: U Sex qualifier: Not applicable Age: 0.00 Day(s) Weight: Unknown	2	2	2	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Indication not indicated / recommended)	06-May-2019	14-Jul-2019*	13 Day(s)	D-A	Mother / offspring SAE case split in two cases. The case was initially reported with both mother and offspring in case 19SE000122. After split of the case, the mother will be reported in the case 19SE000122 and the offspring will be reported in the case 19SE000162. The cases are linked in the MAH database. As reported by the animal owner, a dog, female, pregnant (rough coated miniature dachshund, 6 kg, date of birth 18 JUN 2012, healthy) received FRONTLINE VET SPOT-ON FOR DOGS up to 10 kg (size S) (LOT S20901AX, EXP JUN 2021, valid) topically applied to the area between the shoulder blades, 1 dose given by the owner every 4 weeks on 06 MAY 2019, 03 JUN 2019 and 01 JUL 2019, as treatment against dandruff mites (off-label use, not listed in the local labelling). The owner described that the dog had a bleeding approximately at the same time as product administration or a few days later (not specified after which of the product administrations). The reaction was not treated. The dog was mated on 12 MAY 2019 and gave birth to two pups on 14 JUL 2019. According to the owner both pups were malformed with, among other things, missing ears (not further specified), and had to be euthanised (date not specified). The owner states that no veterinarian has been involved. No information available on the relatedness and inbreeding of this specific mating. Follow up information: As reported by the owner, the bitch had had three litters prior to this one. The owner had used FRONTLINE in the kennel before and also on this bitch. The puppies were born without open ear canal and missing ears, they also had cleft palate and cleft nose. The owner reported this was the first time in 30 years she had seen malformed puppies.
13-Aug-2019	UAE; 19SE000163; -, Sweden	Species: Feline Breed: Domestic Longhair (Crossbreed) Sex: M Sex qualifier: - Age: 1.50 Year(s) Weight: 5 kg	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: FIPRONIL SPRAY; Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	May-2019*	May-2019*	N/A	D-D	As reported by an animal owner (by Social Media and e-mail), a 1.5-year old domestic long hair crossbred (Persian) cat, (male, approx 5 kg, good health) received FRONTLINE VET SPOT-ON 100 MG/ML (batch not given) 1 dose once every month administered topically in the neck by the animal owner since MAY-2019 for tick and flea prevention. In between the spot-on treatments, the owner supplemented with FRONTLINE VET CUTANEOUS SPRAY 2.5 MG/ML (dose unknown) when the she noticed ticks. The owner reported that alive and attached ticks were noticed a few days after product administration. The owner also reported that she had seen single fleas.
13-Aug-2019	UAE; 19SE000165; -, Sweden	Species: Canine Breed: Canine (unknown) Sex: M Sex qualifier: - Age: 14.00 Week(s) Weight: 2.5 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	23-Jul-2019*	10-Aug-2019*	N/A	D-D	As reported by the animal owner, a dog, male puppy, intact, 14 weeks (2.5 kg at first dose, breed unknown) received FRONTLINE COMP for dogs (product unsubstantiated, unknown strength MAH assumed 0.67 ml i.e. 67 mg/60,3 mg, LOT unknown, route and location unknown) dosed according to weight, administered by the animal owner on 23 JUL 2019 approx. (frequency unknown). 18 days after product administration (approx. 10 AUG 2019) the owner reported to have found ticks on the dog.
22-Aug-2019	UAE;	Species: Canine	1	1	0	Product used:	May-2019*	May-2019*	N/A	D-D	As reported by a pharmacist (first contact) and an animal owner

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 135 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00142

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	19SE000168; -; Sweden	Breed: Border Collie Sex: F Sex qualifier: Unknown Age: 4.00 Year(s) Weight: 20 kg				FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes					(primary reporter), a dog, Border Collie, female, intact, 4 years old, 20 kg, received FRONTLINE VET SPOT-ON 100 MG/ML (size L, for dogs bw >20-40 kg) for tick prevention, 1 pipette topically applied by the animal owner in MAY 2019 and JUN 2019. Two doses were given 4 weeks apart. The first dose was from a package from last year (2018, not expired) and the second dose was from a new package bought in 2019 (LOT S20136AX, EXP 12 DEC 2020, valid, stored at room temperature). 2 weeks after product administration the owner noticed attached ticks on the dog. The owner reported that the daughter had been bathing the dog (unknown when). The dog received FRONTLINE in 2018, but it is unknown how the effect was, as the dog was living with the daughter last year.
23-Aug-2019	UAE; 19SE000169; -; Sweden	Species: Feline Breed: - Sex: M Sex qualifier: Neutered Age: 7.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	2019*	2019*	0 Day(s)	D-D	A brief SLEE report from an animal owner. A 7-year old male neutered cat (at good health, breed unknown), received FRONTLINE VET SPOT-ON for cats (LOT unknown) administered by the owner on unknown dates, every 4 weeks. After product administration (time not specified), the owner perceived lack of efficacy (event not further specified).
12-Jul-2019	UAE; 19TR000018; -; Turkey	Species: Canine Breed: Yorkshire Terrier Sex: F Sex qualifier: Unknown Age: 3.00 Year(s) Weight: 6 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-Jun-2019	08-Jun-2019	1 Week(s)	D-D	As reported by the attending vet, a female dog, breed Yorkshire Terrier, birth date 23 JUL 2015, weight 6 kg, good health status at the time of vaccination, was treated on 01 JUN 2019 with FRONTLINE 0,67 ml per Dog (batch 03661103003441, exp date DEC 2019, storage conditions of the product was room temperature), dose unknown, route of application dropping on the skin, by vet for external parasitic control. One week later the dog was back to the veterinarian presenting fleas. The level of vet suspicion is high. The evolution of the event is unknown. This is the extent of information available.
26-Aug-2019	UAE; 19TR000030; -; Turkey	Species: Feline Breed: Feline Other Sex: F Sex qualifier: Unknown Age: 7.00 Month(s) Weight: 2.650 kg	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	10-Jun-2019	30-Jun-2019	20 Day(s)	D-D	SUSPECTED LACK OF EFFICACY: as reported by the attending vet: a CAT (sex female; breed Tabby, 7 months old, weight 2.650 kg, health conditions good but with flea infestation) was treated with FRONTLINE CAT 0,5 ml Dog (batch S21204BW, expiry date 08/2021, pack size 0,5 ml, route dropping on the skin, storage condition: room temperature) on 10 JUN 2019. 20 days later the cat was back to the veterinarian clinic with its flea infestation. The veterinarian applied same product again. 4 days later the flea infestation was continuing. As adding information the cat lives at home. never comes out. The cat came with flea infestation from the pet shop where it was bought. The level of veterinarian suspicion is high. This is the extent of information available.
01-Jul-2019	UAE; 19UK002027; -; United Kingdom	Species: Feline Breed: Feline various breeds Sex: U Sex qualifier: Unknown Age: 3.00 Year(s) Weight: Unknown	4	4	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: Advantage;	N/A	08-May-2019*	N/A	D-D	As reported by the animal owner, four felines, two 3 year old moggies and two 6 year old pedigrees (signalment otherwise unknown) were administered FRONTLINE PLUS SPOT ON CAT (batch and expiry unknown, further details unknown) by the animal owner, after 08 MAY 2019 as a parasiticide. The animal owner reports that three years ago the vet gave one of the animals BROADLINE because she had many fleas. They treated the house and it all settled down. The animal owner was then using

N/A signifies the information for this field is either not available or not applicable

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

Report printed on 25-Oct-2019 at 8:39:59PM

*indicates Approximate date or weight

Page 136 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00143

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Indorex; Route: unknown Was the product used ok?: Unknown to Company					Advantage and everything seemed ok on the animals and so they stopped treating them as they are indoor cats. This was 5 months ago or more. The animal owner has been bitten and so treated the house immediately with Indorex, every two weeks. They saw an advert on television for FRONTLINE PLUS SPOT ON CAT and so ordered some online. They put it on them after 08 MAY 2019. The animal owner has not actually seen any fleas on the cats. The next day, or after, the Cornish Rex boy started to lick himself (veddra code SLEE), and the animal owner thought that it must be the new product. This continued for a while so after a week the animal owner sent for some Advantage. After 2.5 weeks the animal owner had to use Advantage. Once the animal owner used the Advantage the Rex stopped licking. One of the moggies had hoards of flea dirt on her neck but no fleas were seen. The animal owner also has 2 dogs on Stronghold and they are treated at the same time as they treat the cats. The dogs do not go for walks - one of them has bad legs and the animal owner doesn't take one without the other. They do go in the garden. The cat from next door visits the garden and the animal owner is confident that this cat doesn't have anything as they have two small children next door. The animal owner does not want to ask them as they do not want the neighbours to know that they have a problem. The animal owner has carpet in the bedroom, the bathroom and kitchen are tiled, the hallway is small and the living room has vinyl.
02-Jul-2019	UAE; 19UK002029; -; United Kingdom	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: U Sex qualifier: Unknown Age: 6.10 Year(s) Weight: 5.34 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	15-May-2019	16-May-2019	within 12 hours	D-D	6.1 year old 5.34 kg DSH cat had Frontline Combo Spot-on Cat applied on 15 May 2019. Sore, bald patch where product came into contact with skin within 12 hours .
02-Jul-2019	UAE; 19UK002034; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: F Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	01-Jul-2019*	02-Jul-2019	1 Day(s)	D-D	As reported by the animal owner, a female canine (signalment otherwise unknown) was given FRONTLINE SPOT ON DOG M (batch and expiry unknown) 24 hours ago (assumed 01 JUL 2019) topically by the animal owner as a parasiticide. The animal owner reports that the product has been on the dog for 24 hour and it hasn't worked at all. The dog is a new dog and the animal owner flead her before coming home. There are no new fleas that could have jumped on her as their home is completely free as they did not have other pets in the home previously. The product was applied to the dog before coming into the home but the dog still has live fleas. The animal owner now also needs to treat the home.
02-Jul-2019	UAE; 19UK002037; -; United Kingdom	Species: Canine Breed: Retriever Labrador Sex: M Sex qualifier:	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other	N/A	02-Jul-2019	2 Day(s)	D-D	As reported by the animal owner, a male Labrador Retriever canine, weighing 31 kg and in unknown condition, was administered FRONTLINE (assumed FRONTLINE SPOT ON DOG L, batch and expiry unknown, details unknown) by the animal owner, as a parasite product. The animal owner reported that they regularly treat their Labrador Retriever, every calendar month. The

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 137 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00144

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Unknown Age: - Weight: 31 kg				products Route: unknown Was the product used ok?: Unknown to Company					animal is 31 kg and they use the 20-40 kg pipettes. The animal owner states that understandably dogs get ticks, however the animal owner found a very large tick on the animal today, alive, even though he was last treated on Sunday (30 JUN 2019). The tick was fully engorged with blood, had come of by itself and was most certainly not dead.
02-Jul-2019	UAE; 19UK002044; -; United Kingdom	Species: Canine Breed: Retriever Labrador Sex: M Sex qualifier: Neutered Age: 10.00 Year(s) Weight: 32 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: Wormer; Anti-sickness drugs; Pain killer; Route: Topical / Cutaneous Was the product used ok?: Yes	N/A	01-Jul-2019	0 Day(s)	D-B	As reported by the animal owner, Gandhi, an approximately 10 year old male neutered Labrador canine, weighing 32 kg and in unknown condition, was administered FRONTLINE PLUS SPOT ON DOG L (batch S62911AX expiry SEP 2021) topically to an unknown site, by the animal owner, at a dose of 1 pipette on 01 JUL 2019 as a preventative. A wormer was given at the same time. The animal is a rescue dog with unknown history. The dog was reported to be fine on 30 JUN 2019. The product was applied the morning of 01 JUL 2019 at 8 am. At around 10 am the animal had diarrhoea at the end of a walk. The animal was lethargic during the evening walk at approximately 17:30, and showed inappetence at the PM feed and AM feed. The animal would not accept his favourite treats, which he would normally have eaten straight away. On 02 JUL 2019 the animal showed reluctance to walk in the morning, wanting to lie down during the walk, which had to be cut short due to the animal's lethargy. On the walk the animal vomited foamy, stringy vomit. When arriving home the animal would normally go straight to the water bowl, but chose to lay in the shade. The animal owner brought water to the animal, which was drunk. The animal continues to be lethargic. On 03 Jun 2019 the dog deteriorated quickly and the owner took the dog to the local vets. The vet carried out scans and x-rays. The x-rays showed a problem in the dog's abdomen and a mass on the dogs heart. The dog's breathing was also found to be very irregular. The vet administered anti-sickness drugs and a pain killer. The dog was referred to a specialist vet and was taken there on 04 Jul 2019. The dog was booked in for a CT scan that morning however the dog was too poorly to be placed under GA/sedation. An ultrasound was carried out instead which revealed inflammation of the pancreas and tumours within the lungs. The vets at the referral clinic strongly believed it was nothing to do with the FRONTLINE PLUS. The dog remains at the vets and is still under
02-Jul-2019	UAE; 19UK002045; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	02-Jul-2019*	N/A	D-D	As reported by the animal owner, a feline (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON CAT) (batch and expiry unknown) (details unknown) for fleas. The animal owner reported that after a visit to their local vets today, among other things the vet said that the cat was suffering with fleas. The vet asked what treatment the animal owner uses and when they said FRONTLINE, the vet said that it was useless nowadays and that they need to purchase an alternative.
03-Jul-2019	UAE; 19UK002053; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: M Sex qualifier: Unknown Age: 7.00	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other	May-2019	May-2019*	N/A	D-D	As reported by the animal owner, a 7 month old male kitten feline (signalment otherwise unknown) was administered FRONTLINE PLUS SPOT ON CAT (batch S41113AW expiry AUG 2021, further details unknown) for two months by the animal owner, for fleas. The animal owner reports that they have used FRONTLINE products for many years and have been happy. However they have used FRONTLINE PLUS for 2 months on their now 7 month old

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 138 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00145

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Month(s) Weight: Unknown				products Route: unknown Was the product used ok?: Unknown to Company					kitten and are shocked at how many fleas and how much dirt is still on him. The animal owner asks if the product is genuine.
03-Jul-2019	UAE; 19UK002056; Surrey; United Kingdom	Species: Canine Breed: Bulldog Sex: M Sex qualifier: Neutered Age: 9.50 Year(s) Weight: 30 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Yes	30-Jun-2019	30-Jun-2019	0 Day(s)	D-D	As reported by the veterinary nurse, Frankie, a 9.5 year old male neutered Bulldog canine, weighing 30 kg and in good condition, was administered FRONTLINE SPOT ON DOG (assumed FRONTLINE SPOT ON DOG L, batch and expiry unknown, details unknown) by the animal owner on 30 JUN 2019 for an unknown indication. The product was applied on Sunday and they have been taking ticks off every day since. The veterinary nurse said that they didn't know if the ticks had been on the dog since Sunday but that they are happy that the animal owner applied the product correctly. They want to give NEXGARD SPECTRA now.
03-Jul-2019	UAE; 19UK002061; -; United Kingdom	Species: Feline Breed: Norwegian Forest Cat Sex: F Sex qualifier: Neutered Age: 22.00 Month(s) Weight: 5 kg	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	29-Jun-2019	Jul-2019*	13 Day(s)	D-D	As reported by the animal owner, Cooper a neutered female Norwegian Forest Cat aged born on 07 SEP 2017 and weighing 5 kg and in good condition, was given FRONTLINE SPOT ON CAT (batch and expiry unknown) on 29 JUN 2019 topically between the shoulder blades by the animal owner for parasite control. The animal owner reports that they applied the product after seeing Cooper having a bit of a scratch, they did not see any fleas but did notice some scabs around the neck area so they thought it best to treat for fleas. Cooper is a house cat and lives with two other cats, both of which did not receive any flea treatment as there was no scratching going on. Cooper is now licking her foreleg, wiping under her chin and is over washing and over cleaning. She has not made herself sore. The animal owner took the cat to the vet on 03 JUL 2019. The attending vet reports that the cat had pruritic scabs on the dorsal midline, inflamed ventral abdomen, groin and inner thighs, and diagnosed Flea Allergy Dermatitis. The cat was treated with Depo-Medrone injection 0.4 ml subcutaneously. The attending vet believes the clinical signs are due to FAD and not FRONTLINE.
03-Jul-2019	UAE; 19UK002064; -; United Kingdom	Species: Canine Breed: Canine Other Sex: M Sex qualifier: Neutered Age: 8.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	01-Jul-2019	01-Jul-2019	0 Day(s)	D-D	As reported by the animal owner, a male neutered Lurcher canine aged 8 years (signalment otherwise unknown) was given FRONTLINE (assumed FRONTLINE SPOT ON DOG M, batch and expiry unknown) on 01 JUL 2019 topically to the back of the neck by the animal owner because they saw fleas on the dog. The animal owner reports that they are still seeing fleas and have just removed 15 fleas. The animal owner is not being bitten, the dog was untreated when they first noticed lots of fleas on him. The animal owner states that they now live in a different house and the dog still has fleas on him, so feels that the product has not worked. The animal owner is unsure if the product was in date when they used it. The dog was wearing a collar when the product was applied. Start date for submission purposes only.
04-Jul-2019	UAE; 19UK002065; -; United Kingdom	Species: Canine Breed: Retriever Labrador Sex: F Sex qualifier: Neutered Age: 1.67 Year(s)	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical /	N/A	24-Jun-2019	within 12 hours	D-D	Dog administered Frontline Spot on Dog 10% w/v Spot on Solution developed a hot spot on back of neck where spot on applied, alopecia, oozing red broken skin (coded application site moist eczema) in circular lesion within 12 hrs. Reaction duration unknown. Previous exposures but no reactions. UPDATE 26 JUL 2019: The animal owner reported to the MAH that their one year old Labrador Billie, had a reaction to FRONTLINE

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 139 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00146

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: 26 kg				Cutaneous Was the product used ok?: Unknown to Company					SPOT ON FLEA AND TICK TREATMENT. It burned her skin 12 hours after it was applied, leaving some of her without any hair and weeping. The vet said that the cause was the FRONTLINE. The animal had her fur shaved off so that the vet could clean off the FRONTLINE and was put on a course of antibiotics. After almost a month, the hair has grown back and the animal has fully recovered. The animal is a healthy Labrador without any health issues and this was the first serious trip to the vet.
03-Jul-2019	UAE; 19UK002071; Berkshire; United Kingdom	Species: Canine Breed: Canine various breeds Sex: F Sex qualifier: Neutered Age: 9.00 Year(s) Weight: 9.5 kg	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	26-Jun-2019	0 Day(s)	D-D	As reported by the animal owner, Bella, a Collie cross Jack Russell Terrier canine, and Naria, a Jack Russell Terrier cross Chihuahua canine, both 9 years old female neutered, weighing 9.5 kg and in good condition, were administered FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG S) (batch S62709BW expiry SEP 2021) (details unknown) by the animal owner, on 26 JUN 2019 as they saw fleas. The animal owner reports that they have used the product for a good couple of years and never had any issues. The animal owner applied the product a week ago because they saw fleas but the product hasn't worked because they have still got fleas. The animal owner, literally just now, put the flea comb through them and got ten fleas off them. The animal owner is using a household flea spray as per the instructions made by Beaphar. The animal owner shampoos both dogs once a week with a flea shampoo.
03-Jul-2019	UAE; 19UK002072; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	03-Jul-2019*	N/A	D-D	As reported by the animal owner, a dog (signalment otherwise unknown), was treated with FRONTLINE PLUS (estimated as FRONTLINE PLUS SPOT ON DOGS M) batch number: S62911AX and expiry date: SEP 2021, route and frequency unknown, administered by unknown. The owner reported that they were still removing numerous ticks, 3 the other day in various developmental stages. The owner reported that on 02 JUL 2019 they found a large tick in the thick hair of the dog, that was clearly not dead (which was the claim of the product) and the reason for the owner spending the money. The owner was sorely disappointed and was reluctant to put more chemicals on their dog, as it was clearly ineffective. The owner wondered if they could have purchased a duff batch. No further information was supplied. Date of event added for submission purposes only. UPDATE 30 JUL 2019: QA results received - Investigation completed for FIPRONIL 10%/S METHOPRENE 9% SPOT ON Lot# S62911AX, expiry 2021-09-30. Case investigated by France. Final complaint evaluation An adverse event for FRONTLINE PLUS SPOT ON DOGS M, batch number S62911AX, was received by BIAH QA on the 15 of July 2019. This is the first complaint for this batch. The complaint sample is not received. The retention sample is conform (aspect). Batch record review: Bulk batch S629 Manufacturing date: 20/10/2018 - Expiry date: 09/2021 - Manufacturing quantity: 2399 liters. No deviation and observation are associated to this batch and this batch was not concern by any change control. The results of QC testing are conform at specifications. All parameters verified during manufacturing of this batch of bulk are conform. Filling batch S62911 Manufacturing date: 29/10/18 - Expiry date: 09/2021 - Manufacturing quantity: 24 680 blisters. The results of QC testing are conform at specifications. No deviation is associated to this batch and this batch was not concern by any change control. One observation is notified and not associated to this defect

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 140 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

v1.2

ED_005739D_00014390-00147

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
03-Jul-2019	UAE; 19UK002073; -; United Kingdom	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: F Sex qualifier: Unknown Age: 13.00 Year(s) Weight: 5 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: FIPRONIL SPOT ON CAT; Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	07-Apr-2019	Feb-2019*	N/A	D-D	As reported by the animal owner, Luna, a 13 year old female Domestic Short Hair feline, weighing 5 kg and in unknown condition, was administered FRONTLINE PLUS SPOT ON CAT (batch and expiry unknown) topically to the skin just in front of the shoulder blades, by the animal owner at an unknown dose, on 07 APR 2019, 11 MAY 2019, 07 JUN 2019 and 03 MAY 2019 for an unknown indication. The animal owner reports that prior to this they used FRONTLINE SPOT ON CAT. The animal owner reports that the fleas are getting worse and they have been using FRONTLINE PLUS for three months now. The animal owner first noticed fleas on the animal 5 months ago. They try to use the product all year round but didn't do it for some months over the winter. The animal then got a flea infestation and they switched from FRONTLINE to FRONTLINE PLUS. People in the home are being bitten and the animal spends time indoors and outdoors. All animals that live in the house and in-contact animals have been treated with a flea product, the animal owner is seeing many fleas - 5 or more at the same time, the animal never gets bathed or goes swimming and the animal owner has not lived in their home for less than a year. The animal owner has treated the home with an environmental flea treatment, washed the pet's bedding at over 60 degrees and regularly vacuumed all areas that the pet can access.
04-Jul-2019	UAE; 19UK002083; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	Jan-2018*	01-Jul-2019*	N/A	D-D	As reported by the animal owner, a feline (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON CAT, batch and expiry unknown, details unknown) by the animal owner, at a dose of 1 dose monthly for 18 months (estimated to start JAN 2018) for an unknown indication. The animal owner reports that the animal has got fleas again and that they think that the product has stopped working. Start date added for submission purposes only.
05-Jul-2019	UAE; 19UK002088; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	1	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	Jun-2019*	N/A	D-A	As reported by the animal owner, Winks, a feline (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON CAT, batch and expiry unknown, further details unknown) for an unknown indication. The animal owner reports that they have been really pleased with the service but that they are going to try another treatment for their animals due to financial reasons and unfortunately one of their cats, Winks, passed away a few weeks ago.
05-Jul-2019	UAE; 19UK002091; -; United Kingdom	Species: Canine Breed: Terrier Breeds (500 Series) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	4	4	0	Product used: FIPRONIL SPOT ON DOG Other products used: Bravecto; Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, terrier canines (estimated as 4), signalment otherwise unknown) were administered FRONTLINE (assumed FRONTLINE SPOT ON DOG M, batch and expiry unknown, details unknown) at a dose of once every three months for an unknown indication. The animal owner saw fleas and so went to treating monthly. Four months ago the animal owner started using Bravecto. There are still fleas in the house. The animal owner has had the carpets cleaned. Start date added for submission purposes only.

N/A signifies the information for this field is either not available or not applicable

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

Report printed on 25-Oct-2019 at 8:39:59PM

*indicates Approximate date or weight

Page 141 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00148

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
05-Jul-2019	UAE; 19UK002092; -, United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	01-Jun-2019	04-Jul-2019	0 Day(s)	D-D	As reported by the animal owner via social media, approximately 2 canines (signalment otherwise unknown) were administered FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG M, batch and expiry unknown, dosing details unknown) by the animal owner on 01 JUN 2019 and again yesterday, 04 JUL 2019, for fleas. The animal owner reports that they applied the product to their dogs on 01 JUN 2019 and found live fleas on them yesterday, and lots of flea dirt. They were absolutely riddled. The animal owner repeated FRONTLINE PLUS and still there are live fleas today. The animal owner is really disappointed and thought that it lasted 8 weeks.
05-Jul-2019	UAE; 19UK002093; -, United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	2016*	2019*	N/A	D-D	As reported by the animal owner, two felines (signalment otherwise unknown) were administered FRONTLINE SPOT ON CAT (batch and expiry unknown, details unknown) every 4 weeks for a long time (start date estimated as 2016) for an unknown indication. The product was last applied a week and a half ago (estimated as 25 JUN 2019) and the animal owner is still seeing fleas. The animal owner is hoovering like mad and has sprayed the furniture, as well as stopped the animals going into the living room. Start date added for submission purposes only.
06-Jul-2019	UAE; 19UK002097; -, United Kingdom	Species: Canine Breed: Canine (unknown) Sex: F Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	29-Jun-2019	0 Day(s)	D-D	As reported by the animal owner, a female canine (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON DOG M) (details unknown) by the animal owner a week ago (29 JUN 2019) for an unknown indication. The animal owner reports that they used FRONTLINE as directed and one week after application the animal has had three ticks on her with their blood sacs full.
06-Jul-2019	UAE; 19UK002098; -, United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	Jan-2019*	Jan-2019*	N/A	D-D	As reported by the animal owner, a canine (signalment otherwise unknown) was administered FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG M) (batch and expiry unknown) (details unknown) every 4 weeks for 6 months for an unknown indication. The animal owner reports that they are still finding 2 to 3 fleas on the animal every day, and asks if fleas have become immune to the product now as they are disappointed with the results.
06-Jul-2019	UAE; 19UK002099; -, United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products	Jan-2019*	Jan-2019*	N/A	D-D	As reported by the animal owner, a feline (signalment otherwise unknown) was administered FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON CATS) (batch and expiry unknown) (details unknown) every 4 weeks for 6 months for an unknown indication. The animal owner reports that they are still finding 2 to 3 fleas on the animal every day, and asks if fleas have become immune to the product now as they are disappointed with the

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 142 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00149

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: - Weight: Unknown				used: no other products Route: unknown Was the product used ok?: Unknown to Company					results.
06-Jul-2019	UAE; 19UK002100; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	07-Jul-2019	2 Day(s)	D-D	As reported by the animal owner's friend, a feline (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON CAT) (batch and expiry unknown) (details unknown) by the animal owner's friend, on Friday 05 JUL 2019 for fleas treatment. The animal owner's friend reports that they put FRONTLINE on the animal and then sprayed around the house with flea treatment, but they couldn't spray their friend's chair where she and the cat slept together. The animal owner's friend asks if some fleas have got back onto the animal as it seems that their friend has seen one running around the animal's throat today.
07-Jul-2019	UAE; 19UK002101; -; United Kingdom	Species: Feline Breed: Feline various breeds Sex: X Sex qualifier: Unknown Age: 7.00 Year(s) Weight: Unknown	4	4	0	Product used: FIPRONIL SPRAY Other products used: Chloramphenicol ; Advocate; Droncit; Depomedrone; Route: Topical / Cutaneous Was the product used ok?: No (Others)	N/A	01-Jul-2019*	N/A	D-C	As reported by the animal owner, 3 cats, Romeo a neutered male Domestic Shorthair aged 7 years, and 2 further cats, Beany and Itchy, 1 of which was specified as female (signalment otherwise unknown), were treated with FRONTLINE SPRAY (batch number: R01502A and expiry date: FEB 2020), topically, frequency unknown, administered by the cat's owner recently on an unspecified date. After administration, the owner reported that all 3 of the cats had reacted with a burn and their fur had been removed (the fur was coming out in clumps), the cats had cuts and were also bleeding. The owner was shocked that the flea treatment had burned their cats. The owner reported that the cats were in pain and were also itching. One of the cats had 3 legs and was in very bad pain if anything touched the area, the cat screamed and was a very timid cat as it had been living rough for many years in a petrol station with the leg smashed and so it had knitted to her chest. The cat had been taken into a rescue centre 4 years after this had happened and had to have the leg removed, so had suffered enough pain. The other two cats were bleeding and itching and in pain with the burns the product had given them. The cat's did not have fleas they just used the drops to protect them. The owner had contacted her friends to tell them to stop using the treatment at the rescue centre. The owner had sought advice from their vet and the vet was dispensing some antibiotics for the cats. The owner reported that they had always used FRONTLINE on the cats so could not understand why they would have a reaction as they did. The animal owner added that the 3 legged cat is semi feral and cannot go to the vets at all. She has a fear of them and can't go in a cat carrier at all. She won't even go to people she won't know. The animal's back is very bad and if she rolls on it at all she will scream and she can't get up as she has only 3 legs. The FRONTLINE ran down from her neck to her back as it seemed to leak. The
08-Jul-2019	UAE; 19UK002102; -; United Kingdom	Species: Canine Breed: Terrier (Jack Russell) Sex: M Sex qualifier: Neutered	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products	N/A	08-Jul-2019*	N/A	D-D	As reported by the animal owner, Jerry, a neutered male Jack Russel Chihuahua cross breed dog of unknown age, weighing 4 kg and of good health, was treated with 1 pipette of FRONTLINE PLUS (estimated to be FRONTLINE PLUS SPOT ON DOG M) batch number and expiry date unknown, every 4 weeks, administered to the back of the neck by the dog's owner. In the

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 143 of 867

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00150

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: - Weight: 4 kg				used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes					past few days (unknown time since the last dose) the owner reported that they had noticed flea bites all underneath the dog that were very red looking, with some also present on his back. The owner had combed the dog and noticed the red marks under his coat, and has also reported seeing 1 flea. The owner also reported that there were bites on the owner's legs and stomach, as they had noticed the dog sleeping up against the owner's stomach. The owner had fumigated the house, vacuumed and washed all the bedding at 60 degrees. The owner had no other pets other than a tortoise. Date of event added for submission purposes only.
08-Jul-2019	UAE; 19UK002106; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	N/A	09-Jul-2019*	3 Day(s)	D-D	As reported by the animal owner, a male cat (signalment otherwise unknown), was treated with FRONTLINE PLUS SPOT ON CATS (batch number and expiry date unknown), applied by the cat's owner a couple of days previous to the date of the report (date of administration estimated to be 06 JUL 2019). The owner reported on 09 JUL 2019 that the cat was still jumping mid-walk and scratching away which suggested the cat was still being bothered by fleas. The owner wanted to know if they could give the cat a flea tablet. No further information was supplied.
07-Jul-2019	UAE; 19UK002114; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a male canine (signalment otherwise unknown) was administered FRONTLINE SPOT ON DOG S (batch and expiry unknown, details unknown) by the animal owner, for fleas. The animal owner reported that they started to use the product when they first bought their rescue dog, and after a couple of years the animal got fleas and they had to treat the whole house with flea foggers. The animal owner then decided to change to Advocate flea treatment and this was used for some years until they found out that the company were producing neonicotinoid pesticides which were killing their bees, so went back to using FRONTLINE. Now their dog has fleas again and they have just had to treat the house, which the animal owner finds quite annoying. The animal owner asks if fleas are becoming immune to the treatment. Start date added for submission purposes only.
07-Jul-2019	UAE; 19UK002115; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a feline (signalment otherwise unknown) was administered FRONTLINE SPOT ON CAT (batch and expiry unknown, details unknown) for fleas. The animal owner reported to the reporter that while using the product their animal got fleas and so stopped using the products. Start date added for submission purposes only.
09-Jul-2019	UAE; 19UK002118; -; United Kingdom	Species: Canine Breed: Scottish Terrier Sex: M Sex qualifier: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products	08-Jul-2019	08-Jul-2019	0 Day(s)	D-D	As reported by the animal owner, a male Scottish Terrier (signalment otherwise unknown) was given 1 dosage form of FRONTLINE PLUS SPOT ON DOGS M (batch number S60711AL and expiry date FEB 2021) on 08 JUL 2019 topically to the nape of the neck by the animal owner because the dog was scratching a lot. The product was applied at about 1 pm or 2 pm that afternoon.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 144 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

v1.2

ED_005739D_00014390-00151

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: - Weight: Unknown				used: FIPRONIL SPOT ON DOG; Route: Topical / Cutaneous Was the product used ok?: No (Overdose)					In the night, after administration, the dog was going mad scratching and crying all night long. The animal owner then applied another vial of FRONTLINE PLUS the following morning (09 JUL 2019). The dog has received and always responded to FRONTLINE (assumed FRONTLINE SPOT ON DOG M, batch and expiry unknown) in the past, but this time he hasn't really responded.
09-Jul-2019	UAE; 19UK002122; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	3	3	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: Bob Martin; Route: Topical / Cutaneous Was the product used ok?: Yes	21-Jun-2019	09-Jul-2019	18 Day(s)	D-D	As reported by the animal owner, 3 cats (signalment otherwise unknown), of good health, were treated with FRONTLINE PLUS SPOT ON CATS (batch number and expiry date unknown) at a dose of 1 pipette, applied by the owner to the back of the cat's necks on 21 JUN 2019, as a flea treatment, as the owner saw loads of fleas on all of the cats, about 300 fleas. The owner purchased FRONTLINE PLUS and applied it on the 21 JUN 2019. A couple of weeks after it worked the owner said it was really good and they were only really seeing 2 fleas, but now they are seeing more around 6 fleas. The owner was being bitten and was sitting on the laminate flooring and had been able to catch one. The owner reported that before FRONTLINE PLUS the owner was using Bob Martin now and then, but they could not remember the last time they had used it.
09-Jul-2019	UAE; 19UK002123; -; United Kingdom	Species: Canine Breed: German Shepherd Dog Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	Jun-2018*	Jul-2019*	N/A	D-D	As reported by the animal owner, 2 German Shepherd dogs (signalment otherwise unknown), were treated with FRONTLINE PLUS (estimated to be FRONTLINE PLUS SPOT ON DOGS XL) batch number and expiry date unknown, administered by the dog's owner since JUN 2018. The owner reported that they had seen an increase in fleas that are active on the dog's even though they had treated and restricted the area they were in. There had also been a small number of fleas appearing at a house they visited a couple of weeks ago, making them think that flea eggs must have been left there. Date of event added for submission purposes only.
09-Jul-2019	UAE; 19UK002126; -; United Kingdom	Species: Canine Breed: Staffordshire Terrier (American) Sex: M Sex qualifier: Neutered Age: 4.00 Year(s) Weight: 24.1 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: AFOXOLANER 18.75 MG / MILBEMYCIN OXIME 3.75 MG CHEWABLE TABLETS; Indorex; Route: unknown Was the product used ok?: No (Treatment / vaccination program not	N/A	10-Jul-2019	N/A	D-D	As reported by the attending vet, Zac a neutered male Staffordshire Bull Terrier cross canine born on 13 JUN 2015, weighing 24.1 kg and in good condition, was given NEXGARD SPECTRA S (batch number AA1768SAY expiry date AUG 2020) on 04 JUL 2019 at a dose of one dosage form by the animal owner as a parasiticide. The attending vet reports that this is the first dose of NEXGARD SPECTRA the dog has received. The animal has previously had FRONTLINE (assumed FRONTLINE SPOT ON DOG S, batch and expiry unknown) but the animal owner was not compliant. The attending vet saw 3 fleas on the dog in a 10 minute consult. The animal owner also has a cat that was treated last week with Bravecto. The house has been treated with Indorex. The dog goes outdoors for walks.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 145 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00152

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
10-Jul-2019	UAE; 19UK002128; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	respected) Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	10-Jul-2019*	N/A	D-D	As reported by the animal owner, a dog (signalment otherwise unknown), was treated with FRONTLINE (estimated as FRONTLINE SPOT ON DOG M) batch number and expiry date unknown, route and frequency unknown, administered by unknown, on 3 occasions (dates unspecified). On 10 JUL 2019 the owner reported that the dog was still infested with fleas. No further information was supplied.
10-Jul-2019	UAE; 19UK002129; Lancashire; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	10-Jul-2019*	N/A	D-D	As reported by the animal owner, a dog (signalment otherwise unknown), was treated with FRONTLINE (estimated as FRONTLINE SPOT ON DOG M) batch number and expiry date unknown, route and frequency unknown, administered by unknown, on 3 occasions (dates unspecified). On 10 JUL 2019 the owner reported that the FRONTLINE did not work and that it was rubbish and the dog was still crawling with fleas. The owner then went to the vet. No further information was supplied.
10-Jul-2019	UAE; 19UK002134; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: F Sex qualifier: Unknown Age: Kitten Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	08-Jul-2019*	10-Jul-2019	2 Day(s)	D-D	As reported by the animal owner, a kitten (signalment otherwise unknown), was treated with FRONTLINE (estimated as FRONTLINE SPOT ON CAT) batch number and expiry date unknown, route and frequency unknown, by the cat's owner over 24 hours before the date of the report (date estimated as 08 JUL 2019). On 10 JUL 2019 (over 24 hours following product administration) the owner reported that they could still see fleas on the kitten. The owner enquired as to whether they needed to apply another capsule and when the fleas would all die.
11-Jul-2019	UAE; 19UK002139; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	3	3	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: FRONTLINE PETCARE HOME AND ENVIRONMENT FLEA SPRAY; Route: Topical / Cutaneous Was the product used ok?: Yes	N/A	11-Jul-2019	13 Day(s)	D-D	As reported by the animal owner, 3 cats (signalment otherwise unknown) were treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), applied correctly by the owner on 28 JUN 2019 as a parasiticide. On 18 JUL 2019 the owner reported that there were still fleas on the cats, and flea eggs on the furniture (as of 11 JUL 2019). The owner had not seen one dead flea in their house since they applied it. They also had treated the home with FRONTLINE flea killer (assumed to be FRONTLINE PETCARE HOMEGARD HOUSEHOLD FLEA SPRAY) and that did not work either. The owner brought the product from a store and when the owner returned on 17 JUL 2019 they were informed that the product could take up to 3-6 months to work. The owner confirmed that they did apply it correctly. The owner insisted on getting a refund. The cats were still uncomfortable and scratching and the owner was not happy and would never buy the product again. An appointment with the vet had been booked to get another product that actually worked.
10-Jul-2019	UAE;	Species: Canine	1	1	0	Product used:	N/A	06-Jul-2019	0 Day(s)	D-D	As reported by the animal owner, a puppy (signalment otherwise

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 146 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00153

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	19UK002140; -; United Kingdom	Breed: Canine (unknown) Sex: M Sex qualifier: Unknown Age: - Weight: Unknown				FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company					unknown) was given FRONTLINE SPOT ON (assumed FRONTLINE SPOT ON DOG S, batch and expiry unknown) on 06 JUL 2019 via an unknown route given by the animal owner as a parasiticide. The animal owner reports that they have been giving the product monthly (start date unknown) and have not missed any treatments, but the product hasn't killed any of the fleas and now where the dog has been nibbling, he has a small bald patch.
10-Jul-2019	UAE; 19UK002141; -; United Kingdom	Species: Canine Breed: Bedlington Terrier Sex: M Sex qualifier: Neutered Age: 7.00 Year(s) Weight: 10 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Expired)	N/A	09-Jul-2019	0 Day(s)	D-D	As reported by the animal owner, Zigi, a 7 year old male neutered Bedlington Terrier canine, weighing 10 kg and in good condition, was administered FRONTLINE SPOT ON DOG (assumed FRONTLINE SPOT ON DOG S, batch M22613BX expiry NOV 2018) topically to the back of the neck, by the animal owner, at a dose of 1 pipette, on 09 JUL 2019 for an unknown indication. The animal owner saw fleas a couple of days ago and applied FRONTLINE SPOT ON yesterday. The animal owner is still seeing fleas and wants to apply a flea shampoo.
10-Jul-2019	UAE; 19UK002142; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: M Sex qualifier: Unknown Age: 19.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON; Route: unknown Was the product used ok?: Unknown to Company	N/A	May-2019*	N/A	D-D	As reported by the animal owner, Harvey a 19 or 20 year old male feline (signalment otherwise unknown), was treated with FRONTLINE SPOT ON CAT (batch and expiry unknown) (details unknown) by the animal owner when the animal had fleas. The animal owner reported that the animal has gone for quite some time without fleas, but recently they noticed them and so the bought and administered FRONTLINE PLUS SPOT ON CAT (batch number: R40718AW, expiry date: 06-2020), route unknown, on 04 JUN 2019. The animal owner had first noticed the fleas on the cat in mid-MAY 2019, and previously had only treated the cat when he had fleas, and overall not often. Following this application the owner reported that the product did not work at all and that the next day and on subsequent days, the cat still had fleas. The owner could not find information telling them how soon after the first application the FRONTLINE could be reapplied, and so on 09 JUN 2019 (5 days following first product administration) they reapplied the FRONTLINE PLUS, however then reported that it had not worked again. The owner reported that when combing the cat's hair they would find 1 or 2 fleas. The cat goes outside and was not wearing a collar when the product was applied, the owner thoroughly cleaned all of the cat's sleeping areas but not treated the house with a spray, and none of the people in the house were bitten. The owner was upset to see the cat looking so uncomfortable and his balance is not good so when he tries to scratch himself he almost falls over. The owner wondered what she could do and whether it was safe to give him more and also indicated their main area of concern as being the time between treatments as they reported that it was very clearly marked on the FRONTLINE product but they could find no information on the FRONTLINE PLUS treatment product.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 147 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00154

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
10-Jul-2019	UAE; 19UK002143; -; United Kingdom	Species: Canine Breed: Bichon Frise Sex: M Sex qualifier: Unknown Age: 7.00 Year(s) Weight: 7 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: Flea collar; Bob Martin house spray; Bob Martin house powder; Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	01-Jul-2019	07-Jul-2019	6 Day(s)	D-D	As reported by the animal owner, a male Bichon Frise dog aged 7 years and weighing 7 kg (signalment otherwise unknown), was treated with FRONTLINE PLUS SPOT ON DOG S (batch number S6032AL and expiry date JAN 2021) on 01 JUL 2019), by the dog's owner topically to the back of the neck by the animal owner as a parasiticide. The owner reported that the dog had a problem with fleas for some time and so tried FRONTLINE PLUS but in the 2 weeks since administration they had picked no less than 10 fleas off the dog. The owner also reported that they had powdered the house and sprayed the house and treated the dog several times but nothing seems to be working and felt very frustrated as they had spent £24 on the product. The owner asked for further advice on other treatments. In the house there is also one cat, two guinea pigs and one rabbit. The animal owner reports that they use Bob Martin products to treat the house (powder and spray) and the last time the dog and the cat were taken to the vets, neither of them had fleas. The dog, cat and rabbit are all given flea treatments all year round whether fleas are seen or not (product unknown) and the dog and cat wear flea collars all year round. The flea treatment used on Alfie prior to FRONTLINE PLUS (product unknown) was not working as Alfie still had fleas. Alfie had a bath before FRONTLINE PLUS was applied on 01 JUL 2019, then had another bath on 07 JUL 2019 because fleas were noticed, so another FRONTLINE PLUS was applied on the same day. Alfie was bathed again on 11 JUL 2019 as 5 fleas were removed from him last night (10 JUL 2019) and another 6 were removed during the bath. Alfie is mainly a house dog but goes outside to do his business, the cat comes and goes as he pleases but hasn't ever had fleas in the 8 years the animal owner has had him, the fleas only seem to have a taste for Alfie. The rabbit lives outside in a hutch and the guinea pigs live in the house in cages. The animal owner aims to bathe Alfie monthly but
10-Jul-2019	UAE; 19UK002144; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	Apr-2019*	01-Jul-2019*	N/A	D-D	As reported by the animal owner, a cat (signalment otherwise unknown), was treated with FRONTLINE PLUS (estimated as FRONTLINE PLUS SPOT ON CAT), batch number and expiry date unknown, for the last 3 months, route unknown, by the cat's owner. The owner reported that the product did not work as the cat had fleas. The owner also reported that the fleas were in their home and that it will cost them a fortune to get rid of the fleas. The owner's children had also been bitten and the cat was scratching, and is worried the problem is going to get out of control. Start date for submission purposes only.
11-Jul-2019	UAE; 19UK002145; -; United Kingdom	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: F Sex qualifier: Neutered Age: 9.00 Year(s) Weight: 4.3 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Yes	04-Jul-2019	04-Jul-2019*	0 Day(s)	D-D	As reported by the animal owner, Mia a neutered female Domestic Shorthair feline born in 2010 (aged 9 years) and weighing 4.3 kg and in good condition, was given FRONTLINE PLUS SPOT ON CAT (batch number R40718AW expiry date JUN 2020) on 04 JUL 2019 (details otherwise unknown) by the animal owner for parasite control. The animal owner reports that they are not finding FRONTLINE PLUS to be strong enough this year and they do not think the product is working because the cat is still itchy, scratchy, although they are not seeing any fleas. The animal owner has used a spray in the house. The animal owner is getting bites up their arms and believes fleas are the cause of these. Start date for submission purposes only.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 148 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).
Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.
Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00155

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
12-Jul-2019	UAE; 19UK002146; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: M Sex qualifier: Neutered Age: 8.00 Year(s) Weight: 5.00 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	26-Jun-2019	28-Jun-2019	N/A	D-D	Lady applied Frontline Plus (NCA best guessed Frontline Plus Spot-on Cat) to her cat, two days later she noticed that there was a bald patch on the skin where the treatment was administered. Unknown as to why the hair has gone, apart from it is the administration site for the frontline she used 2 days previous. Reaction duration unknown.
11-Jul-2019	UAE; 19UK002149; -; United Kingdom	Species: Feline Breed: Feline (DO NOT USE) Sex: U Sex qualifier: Unknown Age: 3.00 Year(s) Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	Apr-2018*	03-Jul-2019	0 Day(s)	D-D	As reported by the animal owner via Social Media, Roy and Roger, 2 Domestic Shorthair felines, Roy aged 3 years and Roger a female aged 5 years (signalment otherwise unknown) were administered FRONTLINE PLUS SPOT ON CAT (batch and expiry unknown) topically (details unknown) by the animal owner on 04 JUL 2019 to remove fleas. The animal owner reports that it hasn't worked and that they are really disappointed that they still have a problem. The animal owner used the product on the cats twice a year, only over the summer. They saw fleas on 03 JUL 2019 and applied the product on 04 JUL 2019. Prior to this administration, the product was applied in October 2018 and April 2018. People in the home are being bitten by fleas, the cats spend time indoors only, all animals in the house have been treated, the animal owner is seeing occasional fleas, the pets never get bathed or go swimming, the animal owner has not lived in the home for less than a year, the home has been treated with an environmental flea spray, the pet's bedding has been washed at 60 degrees and all areas the pets can access are regularly vacuumed.
11-Jul-2019	UAE; 19UK002150; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	7	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Yes	N/A	06-Jul-2019	0 Day(s)	D-D	As reported by the animal owner, seven felines (signalment otherwise unknown), were administered FRONTLINE PLUS SPOT ON CAT (batch S41113AW expiry AUG 2021) (details unknown) by the animal owner on 06 JUL 2021 for an unknown indication. The animal owner reports that they are still seeing fleas on a couple of the cats. The animals are treated every month and they go outside. The animal owner is sure that there is no home infestation. All the animals are in good health.
11-Jul-2019	UAE; 19UK002156; Bridge end; United Kingdom	Species: Canine Breed: Cockapoo Sex: X Sex qualifier: Mixed Age: 4.00 Year(s) Weight: 8.7 - 11.1 kg	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used	May-2019*	04-Jul-2019	N/A	D-D	As reported by the animal owner, Sooty, born 14 DEC 2014 a male entire Cockerpoo canine, with an estimated weight of 8.7 kg and Ruby, born 14 DEC 2014 a female neutered Cockerpoo canine with an estimated weight of 11.1 kg, both of good health, were treated with FRONTLINE PLUS (estimated as FRONTLINE SPOT ON PLUS DOG M), batch number and expiry date unknown, once a month for the last 2 months, administered correctly, by the dog's owner as they had a problem with fleas. The animal owner reported that the product was not working and that the animal still had fleas after 2 applications. The owner purchased the product on a monthly prescription and now wants to cancel this. Due to the dogs still scratching, becoming distressed and the owner physically

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 149 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00156

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						ok?: Yes					seeing fleas, they took the dog to the vets who advised that the product does not work and hence why they don't sell it any longer. The vet prescribed Advocate advising this will work.
11-Jul-2019	UAE; 19UK002157; -; United Kingdom	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: F Sex qualifier: Neutered Age: 3.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: FIPRONIL SPOT ON CAT; Route: Topical / Cutaneous Was the product used ok?: Yes	2018*	21-Jun-2019*	N/A	D-D	As reported by the animal owner, Pancake a 3 year old, neutered female Domestic Shorthaired feline, of unknown weight and good health, was treated with FRONTLINE PLUS SPOT ON CAT (batch number: S41002AW, expiry date: JUL 2021), correctly administered topically to the back of the neck every 4 weeks, by the cat's owner from last summer (estimated 2018) for an unknown indication. The owner reported that they had used FRONTLINE SPOT ON for years with no problems. The animal owner had moved to FRONTLINE PLUS last summer. The animal owner last applied the product on 24 JUN 2019. A few days before this application they had noticed the cat scratching a lot and that since application they had seen one flea on the cat however the cat was not being bitten.
11-Jul-2019	UAE; 19UK002164; -; United Kingdom	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: X Sex qualifier: Neutered Age: 10.00 Month(s) Weight: Unknown	4	4	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	Mar-2019*	Jul-2019*	N/A	D-D	As reported by the animal owner, 4 domestic shorthaired cats, Buzz and Simba, two 8 year old neutered males, Blue a 10 month old neutered female and Gabe a 10 month old neutered male, weight and condition unknown, were all treated with FRONTLINE PLUS SPOT ON CAT (batch number: S41113AW, expiry date: AUG 2021), starting 4 months ago (estimated MAR 2019), correctly administered topically to the back of the neck every 4 weeks by the cat's owner for an unknown indication. The animal owner reported that after previously using Advocate from their vets they had changed to FRONTLINE PLUS 4 months ago as paying for a consultation was too expensive each time they needed more flea treatment. The owner got the FRONTLINE PLUS from the chemist and applied it to all 4 of the cats every 4 weeks but reported that they saw 5 fleas on the cats and the owner's daughter was also being bitten. The fleas were reported to be mainly on the 2 kittens. The cats do go outside, none of the cats wear collars and the owner reported to have used house spray and had vacuumed everything.
11-Jul-2019	UAE; 19UK002165; -; United Kingdom	Species: Canine Breed: Belgian Sheep Dog Sex: M Sex qualifier: Neutered Age: 9.00 Year(s) Weight: 25 kg	4	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	04-Jul-2019	06-Jul-2019	2 Day(s)	D-C	As reported by the animal owner, Hiroki a 9 year old, neutered male Belgian Shepherd canine, weighing 25 kg and of good health, was treated with FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG L, batch number and expiry date unknown), correctly administered topically by the dog's owner on 04 JUL 2019 for an unknown indication. On 06 JUL 2019 (2 days following product administration) the owner reported that the dog didn't eat, which is unusual as he is a greedy dog, and this continued into Sunday 07 JUL 2019, with the dog also vomiting the food back up if he did eat anything. The owner was confident that the dog didn't lick at the product after application and also reported that the dog was very lethargic. From Saturday 06 JUL 2019 onwards the owner reported that the dog also started going bald down his front legs, back, chest, back legs and underside, became covered in open scabs, that the smell was appalling and that the dog was very uncomfortable and appeared burnt. The dog had a full course of Noroclav and Hibi Scrub was washed on the scabs, which resolved the problem and the dog is now getting better and back to eating normally. All of the owner's other dogs were treated and were fine (estimated 4 dogs in total). This case is linked to 19UK002167.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 150 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00157

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
11-Jul-2019	UAE; 19UK002167; -; United Kingdom	Species: Canine Breed: Collie Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	4	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	04-Jul-2019	04-Jul-2019	0 Day(s)	D-D	As reported by the animal owner, approximately 2 collie canines (signalment otherwise unknown) were administered FRONTLINE PLUS SPOT ON DOG (assumed FRONTLINE PLUS SPOT ON DOG L, batch and expiry unknown) topically to an unknown site, by the animal owner, at an unknown dose, on 04 JUL 2019 for an unknown indication. The animal owner reports that it has worked on her Belgian Shepherd dogs, but feels that it hasn't worked on the collies. The collies are still scratching.
11-Jul-2019	UAE; 19UK002169; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	3	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	11-Jul-2019	11 Day(s)	D-D	As reported by the animal owner, three felines (signalment otherwise unknown) were administered FRONTLINE PLUS SPOT ON CAT (batch and expiry unknown) (details unknown) by the animal owner over two weeks ago (estimated JUN 2019) for fleas. The animal owner reports that the have three cats who have had fleas and so they put FRONTLINE PLUS on them. They also did their 2 dogs with FRONTLINE SPOT ON. This was over 2 weeks ago. Today, 11 JUN 2019, the animal owner has checked them again expecting them to be flea free. Two of the cats have no fleas whatsoever but they are finding some flea muck on the youngest cat of the three (the one that had the most fleas) and this cat still had fleas on her, alive and dead. The animal owner wonders if there is a chance that the FRONTLINE doesn't work on some cats.
12-Jul-2019	UAE; 19UK002170; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: F Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	N/A	12-Jul-2019	18 Day(s)	D-D	As reported by the animal owner, their female cats (signalment otherwise unknown), estimated as 2 cats, were treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), applied by the owner, frequency unknown but the last date of application was on 24 JUN 2019. On 12 JUL 2019 the owner reported that the cat's were itching badly and the owner was itching as well. The owner was also concerned as one of the cat's called Jojo was also pregnant and due to give birth on 25 JUL 2019. The owner did not want an outbreak of fleas when the kittens were around.
12-Jul-2019	UAE; 19UK002175; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: F Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	28-Jun-2019	12-Jul-2019*	2 Week(s)	D-D	As reported by the animal owner, a female feline (signalment otherwise unknown) was given FRONTLINE PLUS SPOT ON CATS (batch and expiry unknown) by the animal owner on 28 JUN 2019 via an unknown route as a parasiticide. The animal owner reports that the cat is an indoor cat, and over two weeks after product administration (12 JUL 2019) the animal owner has only found a single dead flea. They comb the cat daily and she still has fleas. The animal owner is treating the carpets and furnishings and washing the cat's bedding and hoovering daily. Today (12 JUL 2019) on combing the cat for 5 minutes on and off with a flea comb, the animal owner found 12 live fleas, 9 of which were adult fleas.
12-Jul-2019	UAE; 19UK002180;	Species: Canine	1	1	0	Product used: FIPRONIL SPOT	17-Jun-2019	10-Jul-2019	0 Day(s)	D-D	As reported by the animal owner, Bailey, a male Shih Tzu canine aged 7 years, of unknown weight and in unknown condition, was

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 151 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00158

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	-, United Kingdom	Breed: Shih Tzu Sex: M Sex qualifier: Unknown Age: 7.00 Year(s) Weight: Unknown				ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)					treated with FRONTLINE SPOT ON DOG M (batch number: S21001AL, expiry date: JUN 2021), topically to the back of the neck by the animal owner on 17 JUN 2019 as a parasiticide. The owner reported that two days ago (10 JUL 2019) the dog still had fleas. The animal owner put another one on, and again 3 days later the dog still had fleas. The owner was advised FRONTLINE was the best product to use, however reports that clearly it does not work. The owner purchased the product online and states that if it is not fake then the product did not work, which is a big problem. The animal owner report that they first started seeing fleas on 16 JUN 2019, so applied the product on 17 JUN 2019. They treat the dog when they seen fleas or when the dog starts scratching. The animal owner then also applied the product on 24 JUN 2019, 04 JUL 2019 and 16 JUL 2019. People in the home are not being bitten, the dog spends time indoors and outdoors, all animals in the house have been treated, the dog does not bathe or go swimming more than once a week, and this is not within 2 days of applying the product, the animal owner has not lived in their home for less than a year, the home has been treated with an environmental flea treatment, the pet's bedding has been washed at over 60 degrees and all areas the pet can access are regularly vacuumed.
12-Jul-2019	UAE; 19UK002181; -, United Kingdom	Species: Feline Breed: British Shorthair Sex: F Sex qualifier: Neutered Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	08-Jul-2019	08-Jul-2019	0 Day(s)	D-D	As reported by the animal owner, Annie and Pepi, two neutered female British Blue cats, of good health (signalment otherwise unknown), were treated with FRONTLINE PLUS SPOT ON CAT (batch number: S41114AW, expiry date: AUG 2021), correctly administered topically to the back of the neck, by the cat's owner on 08 JUL 2019 for an unknown indication. The animal owner reported that they previously used Advantage on the animals – only in the summer months as this gives them a break from the chemicals in the winter months. They never had fleas before on Advantage. Both cats are indoor cats and so shouldn't get fleas. The animal owner saw fleas at the weekend (estimated 06 JUL 2019) and so purchased FRONTLINE PLUS on Sunday 07 JUL 2019 and applied this on Monday 08 JUL 2019. The animal owner reported that the product doesn't work. They are still seeing fleas on the cats and on the surfaces, with the cats are covered in flea bites and the animal owner can see lots of flea dirt in the coat. The owner reports that the fleas must be multiplying. The owner has sprayed the rooms and that the cats don't wear collars. The animal owner states that their animals have never had fleas until now.
12-Jul-2019	UAE; 19UK002182; -, United Kingdom	Species: Canine Breed: Terrier (Jack Russell) Sex: M Sex qualifier: Unknown Age: 10.50 Year(s) Weight: 7 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	03-Jun-2019	09-Jul-2019	N/A	D-D	As reported by the animal owner, Dougal, a 10.5 year old male Jack Russell Terrier dog, weighing 7 kg and in unknown condition, was treated with FRONTLINE SPOT ON DOG S (batch number S21906AL and expiry date NOV 2021) (details unknown) by the dog's owner on 03 JUN 2019 and again on 10 JUL 2019 for an unknown indication. On 12 JUL 2019 (2 days following product administration) the owner reported that the dog still had fleas running around him, which the owner feels surely should have been killed. The owner also wondered why they are paying more for FRONTLINE, which does not appear to be working. The animal owner reports that they treat the animal when they see fleas and as required. They first noticed fleas on their animals 3 days ago and first started using the product 5 weeks ago. No one in the home is being bitten, the animal spends time indoors and outdoors and they are seeing occasional fleas - less than 5 at the same time. The animal gets bathed or swims less than once a week and the animal owner has treated the home with an environmental flea

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 152 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00159

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											treatment as well as regularly vacuuming all areas that the pet can access.
13-Jul-2019	UAE; 19UK002187; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: F Sex qualifier: Unknown Age: 2.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	N/A	13-Jul-2019	3 Day(s)	D-D	As reported by the animal owner, a 2 year old female cat (signalment otherwise unknown), was treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), applied topically to the back of the cats neck, by the cat's owner on 10 JUL 2019 for an unknown indication. On 13 JUL 2019 (3 days following product administration) the owner reported that the cat had come out in a sore/reaction in the area where the spot on was placed. The cat was fine in herself but the owner wanted to highlight this event in case there had been other reports from the same batch or product. The owner stated that she could not say for definite if the event was caused by the treatment but just wanted to highlight it in case there was an issue with the product.
13-Jul-2019	UAE; 19UK002188; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	N/A	01-Jul-2019*	N/A	D-D	As reported by the animal owner, 2 cats (signalment otherwise unknown), were treated with FRONTLINE (estimated as FRONTLINE SPOT ON CAT), batch number and expiry date unknown, once a month by the cats owner for an unknown indication. The animal owner had been using the product on both their animals every month religiously since they were old enough to have spot on. At the beginning of this month (estimated as 01 JUL 2019) the owner realised they had a flea problem and that both the cats were really suffering. The owner reported that their vet told them that FRONTLINE is not efficient enough. The animal owner had followed the instructions every step of the way and put it on every month, and wanted to know why it had not worked. The owner was extremely disappointed that they had been miss-sold the product especially as when they heard these rumours they had disregarded them as on the website it stated that they were not true and now the owner has an infestation. The owner stated that they would not be buying FRONTLINE again and will be advising all pet owners not to use the products, which they say is not out of spite, but out of concern for the health of animals.
12-Jul-2019	UAE; 19UK002190; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: Milbemax; Panacur; Route: unknown Was the product used ok?: Unknown to Company	N/A	Jul-2019*	N/A	D-C	As reported by the animal owner's mother, a dog (signalment otherwise unknown), was treated with FRONTLINE COMBO (estimated as FRONTLINE COMBO SPOT ON DOGS M) batch number and expiry date unknown, route and frequency unknown, administered by unknown on an unknown date. The mother reported that the dog had now been diagnosed with Lyme Disease by the vet and was a very sick animal. The owner had given the dog only FRONTLINE COMBO along with Milbemax and Panacur, as it's wormer, all of which had been purchased from the vet. The reporter did not want to give any further information.
11-Jul-2019	UAE; 19UK002196; -; United Kingdom	Species: Feline Breed: Persian (No Further Description) Sex: U Sex qualifier:	2	2	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products	05-Apr-2019	05-Apr-2019	N/A	D-D	As reported by the animal owner, two Persian felines (signalment otherwise unknown) were administered FRONTLINE (assumed FRONTLINE SPOT ON CAT, batch and expiry unknown), details unknown) by the animal owner, at an unknown dose for three months from 05 APR 2019 for an unknown indication. The animal owner reports that they wish to make a complaint about the non

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 153 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00160

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Unknown Age: - Weight: Unknown				Route: unknown Was the product used ok?: Unknown to Company					effectiveness of the product for flea treatment. They purchased the product from their vets on 05 APR 2019. They are indoor cats that the animal owner had rescued. They finished the 3 monthly treatment but still have fleas. Further to treatment, the animal owner vacuumed daily, steam cleaned the house, isolated the animals to upstairs, flea combed and bathed them a few days after each treatment. The animal owner believes that they kept their end of the transaction but the product did not. When the animal owner took the animals back to the vet at the end of JUN 2019 the vet found fleas and suggested another brand of treatment.
12-Jul-2019	UAE; 19UK002197; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	Mar-2019	2019*	N/A	D-D	As reported by the animal owner, a cat (signalment otherwise unknown), was treated with FRONTLINE (estimated as FRONTLINE SPOT ON CAT) batch number and expiry date unknown, for 4 months, route unknown, by the animal owner. The owner reported that the product has not been working, and that it has cost them a fortune as they had heard it was the best one, but now they feel like this is not the case. This case is linked to case 19UK002198. Start date added for submission purposes only.
12-Jul-2019	UAE; 19UK002198; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	Mar-2019*	2019*	N/A	D-D	As reported by the animal owner, a dog (signalment otherwise unknown), was treated with FRONTLINE (estimated as FRONTLINE SPOT ON DOG M) batch number and expiry date unknown, for 4 months, route unknown, by the animal owner. The owner reported that the product has not been working, and that it has cost them a fortune as they had heard it was the best one, but now they feel like this is not the case. This case is linked to case 19UK002197. Start date added for submission purposes only.
12-Jul-2019	UAE; 19UK002201; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: No (Treatment / vaccination program not respected)	21-Jun-2019	21-Jun-2019	N/A	D-D	As reported by the animal owner, two felines (signalment otherwise unknown) were administered FRONTLINE PLUS SPOT ON CAT (batch S41303AW and expiry unknown, further details unknown) by the animal owner at a dose of 1 dose on 21 JUN 2019 and again on 01 JUL 2019 for fleas. The animal owner reports that they are very disappointed with their recent purchases. They used the product on their animals on 21 JUN 2019 and it did not kill the fleas on them, nor did it stop the eggs from hatching. The animal owner bought another batch and treated both animals on 01 JUL 2019 - not really wanting to treat them again so soon but they were suffering. This has not worked either. The animal owner reports that they have used FRONTLINE for many years and never had this problem. They query if it is possible that this is a faulty batch. UPDATE 16 AUG 2019: QA results received. Investigation completed for FIPRONIL 10%/S METHOPRENE 12% SPOT ON Lot S41303AW, expiry 2021-10-31. Case investigated by France - Toulouse. Final complaint evaluation A product quality complaint for FRONTLINE PLUS SPOT ON CATS, batch number S41303AW was received by BIAH QA on the 25th of July 2019. The complaint description is: LOE. This is the first complaint regarding this kind of defect for this batch. The complaint sample is not received and pictures are not attached to this case. Not reviewed : the retention sample is stored for identification purposes. Therefore, it is not applicable to this kind of defect.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 154 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).
Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.
Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00161

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											Batch record review: Batch record review: S413 Manufacturing date: 13/11/2018. Expiry date: NA Manufacturing quantity: 999 liters. Associated deviation(s): No deviation associated to this batch Change control associated: This batch was not concerned by any change control. Observation(s): No observation associated to this batch. Results of QC testing: Conform at specifications. All parameters verified during manufacturing of this batch of bulk are conform. Batch record review: S41303. Manufacturing
13-Jul-2019	UAE; 19UK002202; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	5	5	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, five felines (signalment otherwise unknown) were administered FRONTLINE (assumed FRONTLINE SPOT ON CAT) (batch and expiry unknown) (details unknown) by the animal owner for flea control. The animal owner reports that they have five cats that they treat with FRONTLINE and that they struggle keeping up with flea control due to the amount that they pick up everyday in the garden. They also use sprays and flea traps in every room. Start date added for submission purposes only.
14-Jul-2019	UAE; 19UK002204; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	10-Jul-2019	0 Day(s)	D-D	As reported by the animal owner, a male canine (signalment otherwise unknown) was administered FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG M) (batch and expiry unknown) (details unknown) by the animal owner 4 days ago (10 JUL 2019) for an unknown indication. The animal owner reports that they applied FRONTLINE PLUS to their dog 4 days ago but they are still seeing fleas crawling on his skin.
14-Jul-2019	UAE; 19UK002205; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a 12 month old male canine and one other canine (signalment otherwise unknown) were administered FRONTLINE SPOT ON DOG L (batch and expiry unknown) (details unknown) by the animal owner for an unknown indication. The animal owner reports that they recently purchased FRONTLINE 20-40 kg for dogs and has used as advised. One dog seems to not be scratching but the 12 month old dog seems to have them all over him. The animal owner is combing him. The animal owner states that it seems to not be working on him. Start date added for submission purposes only.
15-Jul-2019	UAE; 19UK002206; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Yes	N/A	15-Jun-2019*	N/A	D-D	As reported by the animal owner, a cat (signalment otherwise unknown), was treated with FRONTLINE PLUS (estimated as FRONTLINE PLUS SPOT ON CAT), batch number and expiry date unknown, assumed to be applied on a monthly basis for a matter of months, route unknown, by the cat's owner as a flea and tick treatment. The owner reported that over the last month or so they found 2 ticks really embedded into the cat along with 3 or 4 fleas. The owner had always owned pets, both cats and dogs, and so felt that they were more than aware of how to apply the treatment and they also got others to apply the treatment to the cat for them just to be sure. The owner requested for some information as to why the product wasn't working and a suggestion as to what to do. Date

N/A signifies the information for this field is either not available or not applicable

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

Report printed on 25-Oct-2019 at 8:39:59PM

*indicates Approximate date or weight

Page 155 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00162

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											of adverse event added for submission purposes only.
17-Jul-2019	UAE; 19UK002207; -; United Kingdom	Species: Canine Breed: Collie Sex: F Sex qualifier: Unknown Age: - Weight: 21 - 23 kg	2	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	N/A	17-Jul-2019*	2 Week(s)	D-D	As reported by the animal owner, two female Rough Collie canines weighing 21 kg and 23 kg (signalment otherwise unknown) were given FRONTLINE COMBO SPOT ON DOGS L (batch and expiry unknown) typically at an unknown dose, applied to the back of the neck and the base of the tail, two weeks ago (03 JUL 2019) by the animal owner for parasite control. The animal owner reports that they treat both dogs every 4 weeks with the product and have sprayed the house, washed bedding and they Hoover every day, disposing of the Hoover dust straight away. The animal owner has not had a problem with FRONTLINE in the past and the dogs were washed with a flea shampoo three days ago (14 JUL 2019) and are kept thoroughly groomed as they have long coats. The animal owner has found flea dirt and a few live fleas on one of the dogs. The dogs are irritated by the awful creatures. People in the home are not being bitten. There are hedgehogs and foxes in the garden.
15-Jul-2019	UAE; 19UK002208; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: House spray; Route: unknown Was the product used ok?: Unknown to Company	N/A	May-2019*	N/A	D-D	As reported by the animal owner, 2 cats (estimation) (signalment otherwise unknown), were treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), for a few months, route and frequency unknown, by the cat's owner as a flea treatment. The owner reported that for the last 2 months it has not done a thing. The FRONTLINE reportedly worked for the first week but then after that the cats were covered again. The owner reported that they had deflea'd the house with a spray and their pets with FRONTLINE but they were now covered and losing all their fur. The owner wanted an explanation as to why the product was not working.
15-Jul-2019	UAE; 19UK002210; -; United Kingdom	Species: Canine Breed: Canine Other Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: FIPRONIL SPOT ON DOG; Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner via Social Media, a male Retriever canine (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON DOG M) (batch and expiry unknown) (details unknown) for an unknown indication. The animal owner reports that the product has not worked. The animal is covered in eggs, fleas and goodness only knows what other insect after an application of FRONTLINE and then two weeks later FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG M) (batch and expiry unknown) in the hope that this would work. The animal was not washed before application or after or made wet.
15-Jul-2019	UAE; 19UK002211; -; United Kingdom	Species: Feline Breed: Feline (various breeds) Sex: X Sex qualifier: Unknown Age: 1.00 Year(s) Weight: 5 - 6 kg	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: FRONTLINE PETCARE HOME AND ENVIRONMENT	05-Apr-2019	15-Jul-2019*	N/A	D-D	As reported by the animal owner, Flash a 13 year old, male Devon Rex cat, weighing 6 kg and Mavis a 1 year old, female Savannah cat, weighing 5 kg both cats of unknown health status, were treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), once a month, for the last 4 months (on 05 APR 2019, 05 MAY 2019, 05 JUN 2019 and 05 JUL 2019) applied to the back of the animals neck, as directed, by the animal owner. The owner reported that they were still seeing fleas, not all adult fleas either, they were seeing many fleas 5 or more at the same time. The owner was not being bitten by fleas however. The owner had to bath the cat Flash using an insecticidal shampoo

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 156 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00163

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						FLEA SPRAY; Unspecified flea shampoo; Route: Topical / Cutaneous Was the product used ok?: Yes					because the product just was not working. The owners pets were not exposed to any other animals, the cats were strictly indoor cats. The FRONTLINE products were bought from a pet store. The owner last noticed fleas on the animals in APR 2019. They did not normally have fleas and if they saw any, they dealt with them straight away. The owner was 4 months into trying to eradicate fleas from their house and had also used 4 large tins of FRONTLINE HOMEGARD HOUSEHOLD SPRAY. The animals were bathed or went swimming no more than once a week (but not within 2 days of the product administration). The owners had washed the pet's bedding at over 60°C and had vacuumed all areas the pets could access. The owner had lived in their home for more than 1 year. The owner reported that it was stated that FRONTLINE would break the cycle, but it had not. The owner did not want to keep wasting their money on a product that did not work they would not be buying FRONTLINE again. Date of event added for submission purposes only.
15-Jul-2019	UAE; 19UK002212; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: 18.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: FIPRONIL SPOT ON CAT; Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner via Social Media, an 18 year old feline (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON CAT) (batch and expiry unknown) (details unknown) for an unknown indication. The animal owner reports that the product has not worked. The animal is covered in eggs, fleas and goodness only knows what other insect after an application of FRONTLINE and then two weeks later FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON CAT) (batch and expiry unknown) in the hope that this would work. The animal was not washed before application or after or made wet.
15-Jul-2019	UAE; 19UK002213; -; United Kingdom	Species: Canine Breed: Terrier (Jack Russell) Sex: M Sex qualifier: Unknown Age: 10.00 Year(s) Weight: 7 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: FRONTLINE PETCARE HOME AND ENVIRONMENT FLEA SPRAY; Route: Topical / Cutaneous Was the product used ok?: Yes	05-Apr-2019	Jul-2019*	N/A	D-D	As reported by the animal owner, Baldric a 10 year old, male Jack Russell dog, weighing 7 kg of unknown health status, was treated with FRONTLINE PLUS SPOT ON DOG S (batch number and expiry date unknown), once a month, for the last 4 months (on 05 APR 2019, 05 MAY 2019, 05 JUN 2019 and 05 JUL 2019) applied to the back of the animal's neck, as directed, by the animal owner. The owner reported that they were still seeing fleas, not all adult fleas either, they were seeing many fleas 5 or more at the same time. The owner was not being bitten by fleas however. The dog had to go to the vet to deal with his flea allergy. The owners pet was not exposed to any other animals, the dog went out into the garden, but no-where else. The FRONTLINE products were bought from a pet store. The owner last noticed fleas on the animal in APR 2019. They did not normally have fleas and if they saw any, they dealt with them straight away. The owner was 4 months into trying to eradicate fleas from their house and had also used 4 large tins of FRONTLINE HOMEGARD HOUSEHOLD SPRAY. The animal was bathed or went swimming no more than once a week (but not within 2 days of the product administration). The owners had washed the pet's bedding at over 60°C and had vacuumed all areas the pet could access. The owner had lived in their home for more than 1 year. It stated that FRONTLINE would break the cycle, but it had not. The owner did not want to keep wasting their money on a product that did not work they would not be buying FRONTLINE again. Date of event added for submission purposes

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 157 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00164

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											only.
15-Jul-2019	UAE; 19UK002215; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: No (Indication not indicated / recommended)	N/A	Jul-2019*	16 Day(s)	D-C	As reported by the animal owner, a male cat (signalment otherwise unknown), was treated with FRONTLINE (estimated as FRONTLINE SPOT ON CAT), batch number and expiry date unknown, route and frequency unknown, administered for ear mites, by the cat's owner at the start of this month (estimated as 01 JUL 2019). The owner reported that after this treatment the cat got an ear infection from a scrap with another cat. The owner wondered if they were able to use the treatment again within the same 15 day period and whether or not it will help clear ear mites.
15-Jul-2019	UAE; 19UK002218; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	08-Jul-2019	2 Week(s)	D-D	As reported by the animal owner, 2 cats (signalment otherwise unknown), were treated with FRONTLINE PLUS (estimated as FRONTLINE PLUS SPOT ON CAT), batch number and expiry date unknown, route unknown, by the cat's owner and estimated to be on 24 JUN 2019 as a flea treatment. On 08 JUL 2019 (2 weeks following product administration) the owner reported that both the cats were still infested with fleas rendering the treatment useless as they had been advised not to use another product until the first treatment had worn off. The owner reported that they now have to wait almost a month to resolve this and they would not have had to if the product had worked in the first place. The owner was advised to purchase FRONTLINE by the assistant in their local supermarket, although this was the most expensive product and the owner felt the least effective. The owner reportedly paid £70 for the last lot and is now going to have to pay more money which they cannot really afford.
15-Jul-2019	UAE; 19UK002219; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	08-Jul-2019	2 Week(s)	D-D	As reported by the animal owner, a dog (signalment otherwise unknown), was treated with FRONTLINE PLUS (estimated as FRONTLINE PLUS SPOT ON DOG M), batch number and expiry date unknown, route unknown, by the dog's owner and estimated to be on 24 JUN 2019 as a flea treatment. On 08 JUL 2019 (2 weeks following product administration) the owner reported that the dog was still infested with fleas rendering the treatment useless as they had been advised not to use another product until the first treatment had worn off. The owner reported that they now have to wait almost a month to resolve this and they would not have had to if the product had worked in the first place. The owner was advised to purchase FRONTLINE by the assistant in their local supermarket, although this was the most expensive product and the owner felt the least effective. The owner reportedly paid £70 for the last lot and is now going to have to pay more money which they cannot really afford.
16-Jul-2019	UAE; 19UK002220; Devon; United Kingdom	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: M Sex qualifier: Neutered Age: 9.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical /	Sep-2018*	04-Jun-2019*	0 Day(s)	D-D	As reported by the animal owner, Miffy a neutered male feline aged 9 years and in good condition (signalment otherwise unknown), was given one dosage form of FRONTLINE PLUS SPOT ON CAT (batch and expiry unknown) 6 weeks ago (estimated 04 JUN 2019) topically to the back of the neck by the animal owner for parasite control. The animal owner reports that they have used the product on the cat since SEP 2018 and they have never had any problems. The product was applied 6 weeks ago and the animal owner noticed fleas. They waited 4 weeks and applied the product again.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 158 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00165

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Cutaneous Was the product used ok?: Yes					The animal owner is still seeing fleas but they are not sure why. They have sprayed the house twice and vacuumed. No one in the house is being bitten.
17-Jul-2019	UAE; 19UK002225; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: FIPRONIL SPOT ON CAT; Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, approximately 2 cats (signalment otherwise unknown), were treated with FRONTLINE SPOT ON CAT (batch number and expiry date unknown), details unknown by the animal owner for an unknown indication. The animal owner reported that they had been using FRONTLINE with success for some time. They decided to upgrade to FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), but the cats are scratching and the animal owner is being bitten by tiny little buggers. They have now bought some household spray to get rid of them. The animal owner does not have carpets but has sprayed the mats and furniture. Start date of event estimated for submission purposes.
17-Jul-2019	UAE; 19UK002231; Hampshire; United Kingdom	Species: Canine Breed: Canine Other Sex: M Sex qualifier: Unknown Age: 4.00 Year(s) Weight: 27 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Others)	05-Jul-2019	05-Jul-2019	0 Day(s)	D-D	As reported by the animal owner, Vinne a male Munsterlander dog aged 4 years and weighing 27 kg (signalment otherwise unknown) was treated with FRONTLINE SPOT ON DOG L (batch number: S21403AL and expiry date: SEP 2021), topically between the shoulder blades by the animal owner as a flea treatment on 05 JUL 2019. The animal owner reported that they bought the product online and applied 1 pipette as directed. The owner treated all other areas of the house. The owner checked the dog daily with a nit comb expecting the fleas to all have been killed and no further major infestation. The owner reported that the dog has continued to have a number of fleas each day, on 17 JUL 2019 catching approximately 30. The owner reported that the product does not seem to have had any effect on the fleas. The owner is continuing to treat the house and furnishings but has seen no signs of them anywhere else. The owner asked if there was a problem with this batch and what should they do as it says not to reapply more regularly than 4 weeks. The animal owner reports that they use the product all year round, they started seeing fleas in early July and have seen them continuously since then, people in the home are not being bitten by fleas, the dog spends time inside and outside, all animals in the household have been treated, the animal owner is seeing many fleas at a time, some of them are big and mature and some are small or minute, the dog goes swimming more than once a week in sea water but this is not within 2 days of product application, the animal owner has not lived in the home for less than 1 year, the home has been treated with an environmental flea treatment, the pet's bedding has been washed at over 60 degrees Celsius and all areas the pet can access are regularly hoovered. The animal owner reports that they are not sure they are able to remove all the fleas manually (with a flea comb) which is why they purchased FRONTLINE. The animal owner does not believe there is a home
17-Jul-2019	UAE; 19UK002235; -; United Kingdom	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: F Sex qualifier:	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products	N/A	03-Jul-2019	N/A	D-D	As reported by the animal owner, Amber a 10 year old neutered female, Domestic Shorthair cat, weighing 4 kg and of good health was treated with FRONTLINE SPOT ON CAT (batch number: S20308AW, expiry date: FEB 2021), administered topically to the back of the neck every 4 weeks except in the winter months for many years, by the cat's owner for an unknown indication. The

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 159 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00166

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Neutered Age: 10.00 Year(s) Weight: 4 kg				Route: Topical / Cutaneous Was the product used ok?: Yes					owner reported that they applied the FRONTLINE every month, except during the winter months as the frost kills the fleas. The owner reported that it has been fine this year until recently and has noticed fleas biting the cat. The owner last applied the FRONTLINE 2 weeks ago and wondered if another could be applied. The owner wondered if this was a bad batch and reported that no one in the house was being bitten. The owner does have a house spray to use and also has a hedgehog in the garden and asked if that could be where the fleas are coming from. UPDTAE 28 AUG 2019: QA results received. Investigation completed for FIPRONIL SPOT ON CAT Lot S20308AW, expiry 2021-02-28. Case investigated by France - Toulouse. Final complaint evaluation: A product quality complaint for FRONTLINE SPOT ON CAT, batch number S20308AW, was received by BIAH QA on the 25th of July 2019. The complaint description is: lack of efficacy. This is the 3rd complaint regarding this defect for this batch. The complaint sample is not received and pictures are not attached to this case. Retention sample not reviewed : the retention sample is stored for identification purposes. Therefore, it is not applicable to this kind of defect. Batch record review: Batch record investigation Bulk batch: S203. Manufacturing date: 05/03/2018 - Expiry date: NA - Manufacturing quantity: 1199 liters. No deviation and observation associated to this batch. This batch was not concerned by any change control. Results of QC testing are conform at specifications. All parameters verified during manufacturing of this batch of bulk are conform. Batch record
17-Jul-2019	UAE; 19UK002239; -; United Kingdom	Species: Feline Breed: Domestic Longhair (Crossbreed) Sex: F Sex qualifier: Neutered Age: 8.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	19-Jun-2019	19-Jun-2019	N/A	D-D	As reported by the animal owner, Maisie, an 8 year old, neutered female Domestic long hair cat, of unknown weight and of good condition was treated with FRONTLINE SPOT ON CAT (batch number and expiry date unknown), administered topically to the back of the neck every 2 weeks since 19 JUN 2019 by the animal owner for an unknown indication. The owner reported that they had used FRONTLINE and its not working. They reported that they are still seeing fleas on the cat and that the cat has flea allergies so she is scratching a lot and losing fur. The cat is an RSPCA neglect case and was bald from flea allergies when she was rescued. The owner has sprayed the house and got an electric zapper. The owner got FRONTLINE because it is the most expensive and the best but it hasn't worked. The owner reported that they only had 1 rug in the house so they can't live anywhere else in the house, and they know that its nothing that they are doing wrong. The product was purchased from a large pet shop and the owner is being nibbled a bit.
17-Jul-2019	UAE; 19UK002242; -; United Kingdom	Species: Canine Breed: Shih Tzu Sex: M Sex qualifier: Unknown Age: 15.00 Year(s) Weight: 8 - 9 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	10-Apr-2019	10-Jul-2019	0 Day(s)	D-D	As reported by the animal owner, Busby, a 15 year old male Shih-tzu, weighing between 8 and 9 kg (signalment otherwise unknown) was treated with FRONTLINE SPOT ON DOG (estimated as FRONTLINE SPOT ON DOG S) (batch S21204BW expiry AUG 2020) for the past 3 months, administration route unknown, by the animal owner for an unknown indication. The owner reported that they first treated the dog on 10 APR 2019 and have reapplied the product on the 10 MAY 2019, 10 JUN 2019 and the 10 JUL 2019, however the owner does not apply FRONTLINE all year round, instead they only treat the dog when they notice he needs to be treated and if they need the treatment they use it once a month. 5 months ago the owner noticed fleas on their cat and so purchased both FRONTLINE SPOT ON DOG and FRONTLINE SPOT ON CAT. The owner reported that they have used all 3

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 160 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00167

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											packs and have seen no improvements with the fleas, in fact it has got worse. The dog is still infested with fleas. The owner reported that people in the house are being bitten, they are seeing several fleas on their pets and that their cat does not go outside. The owner has not yet treated the house with a spray because they thought that the FRONTLINE would work and they hoovered the house regularly and used a carpet cleaner. The product was not applied whilst their pet was wearing a collar, and their pets do not go swimming and they try to bathe them whenever needed, they would say about every few months or whenever needed. Case linked to case 19UK002243.
17-Jul-2019	UAE; 19UK002243; -, United Kingdom	Species: Feline Breed: Feline various breeds Sex: F Sex qualifier: Unknown Age: 2.00 Year(s) Weight: 5 kg*	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	10-Apr-2019	10-Jul-2019	0 Day(s)	D-D	As reported by the animal owner, Willow, a 2 year old female cross breed cat, weighing about 5 kg (signalment otherwise unknown) was treated with FRONTLINE SPOT ON CAT (batch S21204BW expiry AUG 2020) for the past 3 months, administration route unknown, by the animal owner for an unknown indication. The owner reported that they first treated the cat on 10 APR 2019 and have reapplied the product on the 10 MAY 2019, 10 JUN 2019 and the 10 JUL 2019, however the owner does not apply FRONTLINE all year round, they only treat the cat when they notice she needs to be treated and if they need the treatment they use it once a month. 5 months ago the owner noticed fleas on their cat and so purchased FRONTLINE SPOT ON CAT. The owner reported that they have used all 3 packs and have seen no improvements with the fleas, in fact it has got worse. The cat is still infested with fleas. The owner reported that people in the house are being bitten, they are seeing several fleas on their pets and that their cat does not go outside. The owner has not yet treated the house with a spray because they thought that the FRONTLINE would work and they hoovered the house regularly and used a carpet cleaner. The product was not applied whilst their pet was wearing a collar, and their pets do not go swimming and they try to bathe them whenever needed, they would say about every few months or whenever needed. Case linked to case 19UK002242.
18-Jul-2019	UAE; 19UK002248; -, United Kingdom	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: M Sex qualifier: Unknown Age: 12.00 Year(s) Weight: 4.000 kg*	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	Jun-2019*	5 Week(s)	D-D	As reported by the animal owner, Crispin, a 12 year old male Domestic Shorthair cat weighing approximately 4 kg (signalment otherwise unknown) was treated with FRONTLINE SPOT ON CAT (batch number S21017AW and expiry date JUN 2021) details unknown, by the animal owner for their cat's flea problem on 18 JUN 2019. The owner reported that they were very disappointed as the product did not work at all. The owner reported that the product cost them £20 and that they still have 2 vials left. The owner reported that they followed the instructions correctly but it had absolutely no effect on their cat. The owner had to go to their vet and purchase another product from them which has worked. The animal owner reports that they treat the animal when he starts going out hunting in the spring and continues over spring and summer. The animal owner applies the product as the instructions on the packet told them to and no people in the house are being bitten by fleas. The animal spends time indoors and outdoors, all in-contact animals have been treated, the animal never gets bathed or goes swimming and the animal owner is seeing many fleas - more than 5 at the same time. The animal owner has treated the home with an environmental flea treatment, washed the pet's bedding at over 60 degrees and regularly vacuumed all areas that the animal can access. Date of event added for submission purposes only.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 161 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00168

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
18-Jul-2019	UAE; 19UK002252; -, United Kingdom	Species: Feline Breed: Feline (unknown) Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	Jul-2019*	0 Day(s)	D-D	As reported by the animal owner, a male cat (signalment otherwise unknown) was treated with FRONTLINE PLUS SPOT ON CAT, batch number and expiry date unknown, details unknown, for many months by the animal owner for an unknown indication. The animal owner reported that they applied FRONTLINE PLUS to their cat this week (estimated as 15 JUL 2019) and noticed his hair has all fallen out on the site of application. The owner has used this product for many months but this is the first time they have noticed this side effect. The owner also reported that the cat is well otherwise but she is concerned.
18-Jul-2019	UAE; 19UK002253; -, United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	09-Jul-2019	N/A	D-D	As reported by the animal owner, a dog (signalment otherwise unknown), was treated with FRONTLINE (estimated as FRONTLINE SPOT ON DOG M), batch number and expiry date unknown, details unknown, by the animal owner on 09 JUL 2019 for an unknown indication. The owner reported that they had treated their dog and cats with FRONTLINE but they are still scratching and they have seen fleas on their dog. The owner wondered if they could re-treat. This case is linked to case 19UK002254.
18-Jul-2019	UAE; 19UK002254; -, United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	09-Jul-2019	0 Day(s)	D-D	As reported by the animal owner, 2 cats (estimated, signalment otherwise unknown), were treated with FRONTLINE (estimated as FRONTLINE SPOT ON CAT), batch number and expiry date unknown, details unknown, by the animal owner on 09 JUL 2019 for an unknown indication. The owner reported that they had treated their dog and cats with FRONTLINE but they are still scratching and they have seen fleas on their dog. The owner wondered if they could retreat. This case is linked to case 19UK002253.
18-Jul-2019	UAE; 19UK002255; -, United Kingdom	Species: Canine Breed: Staffordshire Terrier (American) Sex: U Sex qualifier: Unknown Age: 1.00 Year(s) Weight: 42 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	27-Jun-2019	18-Jul-2019	3 Week(s)	D-D	As reported by the animal owner, a 1 year old Staffordshire bull terrier cross dog, weighing 42 kg (signalment otherwise unknown) was treated with FRONTLINE SPOT ON (assumed FRONTLINE SPOT ON DOG XL, batch number: S21516AX, expiry date: SEP 2020), administered topically to an unknown site, by the animal owner on 27 JUN 2019 to treat fleas. The owner asked on 18 JUL 2019 if the product can be applied more frequently than every 4 weeks. The owner reported that the last application was 3 weeks ago and that the dog is having a bit of an itch and scratch and they have seen the odd flea. The owner noticed the event on 18 JUL 2019.
17-Jul-2019	UAE; 19UK002257; -, United Kingdom	Species: Canine Breed: Terrier (Jack Russell) Sex: F Sex qualifier: Neutered Age: 14.00 Year(s) Weight: 5 kg*	4	4	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: Indorex;	N/A	17-Jul-2019	approximately 4 weeks	D-D	As reported by the owner, via a distributor, 4 dogs (one of the dogs detailed as Harry a 14 year old, neutered female Jack Russell Terrier dog, weighing approximately 5 kg), were treated with FRONTLINE PLUS SPOT ON DOGS S (batch number: S60812AL and expiry date: 31 MAR 2021) at a dose of 0.67ml, applied to the dog's neck by the owner on 08 JUL 2019, administered by the animal's owner, as preventative care. On 17 JUL 2019 (approximately 1 month following product administration), the

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 162 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00169

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Route: Topical / Cutaneous Was the product used ok?: Yes					owner reported to the distributor that Harry and the other 3 dogs were very itchy with fleas. The fleas had been physically seen on Harry the other dogs were itching but no fleas had been seen. Harry was more sensitive to fleas than the other dogs and had been taken to the vet. The vet suggested that the FRONTLINE was not working and gave the dog steroid treatment. Harry was also bathed to soothe the itching. The owners 3 cats were also treated (with another batch of FRONTLINE PLUS no details were supplied) but they were fine as they were not in the house as much. Indorex house spray had been used routinely and the animals bedding had been hoovered but not washed. On 18 JUL 2019 the owner's wife reported that the people in the house were being bitten and all the animals now had lots of fleas. They had been using FRONTLINE for many years with no problems seen and had always applied every 4 weeks to all the animals. The product was very expensive so they had now moved onto Advocate.
17-Jul-2019	UAE; 19UK002258; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	3	3	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: Indorex; Route: unknown Was the product used ok?: Unknown to Company	N/A	18-Jul-2019	10 Day(s)	D-D	As reported by the owner, via a distributor, 3 cats (signalment otherwise unknown), were treated with FRONTLINE PLUS SPOT ON CATS (batch number and expiry date unknown), administered by the animal's owner, as preventative care (the owners 3 dogs had also been treated case: 19UK002257). On 17 JUL 2019, the owner reported to the distributor that the 3 cats were fine as they were not in the house as much. Indorex house spray had been used routinely and the animals bedding had been hoovered but not washed. On 18 JUL 2019 the owner's wife reported that the people in the house were being bitten and all the animals now had lots of fleas. They had been using FRONTLINE for many years with no problems seen and had always applied every 4 weeks to all the animals. The product was very expensive so they had now moved onto Advocate.
18-Jul-2019	UAE; 19UK002262; -; United Kingdom	Species: Canine Breed: Spaniel (Welsh Springer) Sex: F Sex qualifier: Unknown Age: 11.50 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: FIPRONIL SPOT ON DOG; Route: unknown Was the product used ok?: Unknown to Company	19-Aug-2018	Jul-2019*	30 Day(s)	D-D	As reported by the animal owner, Nessie, an 11.5 year old female Welsh Springer Spaniel canine, of unknown weight and condition, was administered FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG M, batch P62213bl expiry AUG 2021, further details unknown) on 19 AUG 2018, 19 MAY 2019 and 19 JUN 2019 for an unknown indication. The animal owner reports that they are seeing 2 to 3 fleas a day and have only been seeing them the last month. The animal does no swimming and is bathed occasionally. The animal owner reports that humans are not being bitten, they have not treated the house and it is meticulously clean. The animal owner has lots of experience with dogs, showing, working and breeding and in the past owning large kennels, and they used to use FRONTLINE (assumed FRONTLINE SPOT ON DOG M) for years successfully, but they can't get rid of them. The animal owner also has a cat that is treated with FRONTLINE PLUS and there are no fleas on the cat. The animal owner reports that the product is not working in keeping their dog flea free as it has done in the past over many years. The animal owner added on 20 JUL 2019 that they have seen quite a few fleas on their dog, around her teats, when they have examined her underside. The animal owner states that they cannot recall having seen so many fleas as this ever, especially after using the treatment that has always in the past kept these critters at bay. The animal owner reports that the dog is itching a lot. The animal is 14 inches at the shoulder and is not fat or overweight. They do not have a suitable scale at home and the vets are shut at weekends and so they

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 163 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00170

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											cannot provide the weights. The animal owner reports that they have a cat which is on the smallish side of medium (no further details provided about this animal).
18-Jul-2019	UAE; 19UK002263; Surrey; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, 2 cats (signalment otherwise unknown), were treated with FRONTLINE SPOT ON CAT (batch number and expiry date unknown), administered topically to the back of the neck, by the animal owner for many months, applying it every 4 weeks throughout the winter, spring and summer for an unknown indication. The owner reported that they last applied a pipette to both cats a few weeks ago and then 10 days after that, and they were aware this is probably wrong to do. The owner reported to be spraying the house, washing bedding and vacuuming. The owner reported that people in the house are being bitten a bit on the ankles but only when they pick the cats up. The owner also reported that both cats are indoor cats and that they believe that the cats are resistant to the product.
18-Jul-2019	UAE; 19UK002264; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: F Sex qualifier: Unknown Age: 14.50 Year(s) Weight: Unknown	1	1	1	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: FIPRONIL SPOT ON DOG; Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-A	As reported by the animal owner, a 14.5 year old female canine (signalment otherwise unknown), was administered FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG M, batch and expiry and details unknown) for an unknown indication. The animal owner has lots of experience with dogs, showing, working and breeding and in the past owning large kennels, and they used to use FRONTLINE (assumed FRONTLINE SPOT ON DOG M) for years successfully. The animal was recently put to sleep as had vestibular syndrome. The animal owner also has a cat that is treated with FRONTLINE PLUS and there are no fleas on the cat.
19-Jul-2019	UAE; 19UK002265; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	6	6	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	2019*	2019*	N/A	D-C	As reported by the animal owner, 6 cats, 1 large male British short hair (Caesar), 1 kitten, and 4 others (signalment otherwise unknown) were treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), details unknown, by the animal owner on an unknown date for an unknown indication. The owner reported that her large male British short hair cat had developed 2 large burns after they used FRONTLINE PLUS SPOT ON on him. The owner also reported that they had used it in all 6 of their cats and all still have live fleas which were introduced on a new kitten. The owner requested a refund for all 6 and comments on Caesar's burns and lack of flea death. Clinical sign start date added for submission purposes only.
19-Jul-2019	UAE; 19UK002266; -; United Kingdom	Species: Feline Breed: British Shorthair Sex: M Sex qualifier: Neutered Age: - Weight: 4 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: FIPRONIL SPOT ON CAT; Route: Topical / Cutaneous Was the	N/A	18-Jul-2019	1 Day(s)	D-D	As reported by the animal owner, Ashley a neutered male British Blue cat, weighing 4 kg and of unknown age and condition was treated with FRONTLINE PLUS SPOT ON CAT (batch number: S41306, expiry date: OCT 2021), administered topically to the back of the neck by the cats owner once a month, all year round, on the 17th of each month starting recently for an unknown indication. The owner reported that they had only just started using the FRONTLINE PLUS, and that before it was the normal FRONTLINE (estimated as FRONTLINE SPOT ON CAT). The owner reported that they were very disappointed in FRONTLINE PLUS. The owner reported that they had bought it thinking it would be powerful but it has been fairly useless in controlling fleas. The owner reported that

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 164 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00171

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						product used ok?: Unknown to Company					they comb the cat every day and that they are glad they do because despite using the FRONTLINE the get live fleas from the cat's coat. The owner has flea bites too. The owner reported that for an expensive product it does seem to be ineffective and that they think their money has been wasted. The owner reported that they noticed the fleas the day after using the FRONTLINE PLUS. They reported that their cat is an only pet it is mainly an indoor cat but does go out occasionally and that the cat does get groomed but not bathed. The owner vacuums regularly and has lived there for several years. The owner reported that their home was not flea infested and that the cat has his FRONTLINE every month and that they have never had this situation before.
19-Jul-2019	UAE; 19UK002271; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	16-Jul-2019	16-Jul-2019	0 Day(s)	D-D	As reported by the animal owner, a canine (signalment otherwise unknown) was administered FRONTLINE SPOT ON (assumed FRONTLINE SPOT ON DOG M, batch and expiry unknown, details unknown) three days ago (16 JUL 2019) for an unknown indication. The animal owner reports that they purchased the product online. They used the product and it did not work at all. The animal owner thinks that it is fake and they are worried as to what they have given to their pet dog. The product has been on the dog for three days now. Start date added for submission purposes only.
19-Jul-2019	UAE; 19UK002273; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a male cat (signalment otherwise unknown), was treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), details unknown, by the animal owner on an unknown date for an unknown indication. The owner reported that they are using FRONTLINE PLUS on their cat but he spends a lot of time outdoors and picks up the odd flea so they wish to use a flea collar too and asked whether it is safe to use a flea collar with FRONTLINE PLUS. Start date of event added for submission purposes only.
20-Jul-2019	UAE; 19UK002276; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: FIPRONIL SPOT ON CAT; Route: unknown Was the product used ok?: Unknown to Company	2019*	2019*	0 Day(s)	D-D	As reported by the animal owner, an estimated 2 cats (signalment otherwise unknown), were treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), details unknown, by the animal owner recently for an unknown indication. The owner reported that they have always used regular FRONTLINE (estimated as FRONTLINE SPOT ON CAT, batch number and expiry date unknown) on their cats and never had a problem, but this FRONTLINE PLUS does not work. The owner reported that they have read the instructions and have administered it correctly, they have had cats for 11 years and know what they are doing. The owner reported that they may as well have put water on their cats for the same outcome and they don't have the money to waste on a product that does not work and will not use any more of the pipettes. Start date of even added for submission purposes only.
20-Jul-2019	UAE; 19UK002277; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products	29-Jun-2019*	20-Jul-2019	3 Week(s)	D-D	As reported by the animal owner, a dog (signalment otherwise unknown), was treated with FRONTLINE (estimated as FRONTLINE SPOT ON DOG M), batch number and expiry date unknown, details unknown, 3 weeks ago (estimated as 29 Jun

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 165 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00172

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: Unknown Age: - Weight: Unknown				used: no other products Route: unknown Was the product used ok?: Unknown to Company					2019) by the animal owner as a parasiticide. The owner asked how often should FRONTLINE be applied. The owner reported that they applied it 3 weeks ago and have just removed a new tick.
20-Jul-2019	UAE; 19UK002280; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	20-Jul-2019*	1 Day(s)	D-D	As reported by the animal owner, a male dog (signalment otherwise unknown) was treated with FRONTLINE SPOT ON (estimated as FRONTLINE SPOT ON DOG M), batch number and expiry date unknown, details unknown, by the animal owner estimated as on 19 Jul 2019. The owner reported that they had applied FRONTLINE for their dog's size and yet he is still itching 24 hours on.
21-Jul-2019	UAE; 19UK002282; -; United Kingdom	Species: Canine Breed: Spaniel (Cocker) Sex: X Sex qualifier: Unknown Age: - Weight: 11.000 - 13 kg	3	3	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: FRONTLINE PETCARE HOME AND ENVIRONMENT FLEA SPRAY; Route: Topical / Cutaneous Was the product used ok?: Yes	12-Jul-2019	12-Jul-2019*	0 Day(s)	D-D	As reported by the animal owner, 3 Cocker Spaniel dogs (Woody-an 11kg Male, Spud a 13kg male, Eva-a 12kg female), were treated with FRONTLINE PLUS SPOT ON DOG M, batch number and expiry date unknown, details unknown, by the animal owner for an unknown indication on 12 JUL 2019. The owner reported that they cleaned their kennels, changed their bedding and washed it at over 60 degrees Celsius, treated their house with FRONTLINE PETCARE HOMEGARD HOUSEHOLD SPRAY 400 ML and regularly vacuumed all areas the pets can access. The owner reported however that they checked the dogs yesterday (20 Jul 2019) and they are still crawling with fleas. The owner is not impressed at all as the product is expensive and they expect them to work. The owner reported that they treat each of their pets when they see fleas and only use the product when it is needed and not all year round. The owner reported that they applied the product by following the instructions. They parted the fur and poured onto the skin at the base of the neck. The owner also reported that no people in the home are being bitten by the fleas and that the dogs spend time indoors and outdoors (garden, park), and that all the animals that live in the household and in contact animals have been treated with a flea product. The owner reported that they are seeing more than 5 fleas at a time on their pets and that their pets do not go swimming more than once a week, and they do not swim or bathe within 2 days of product application. The owner has lived in their house for more than a year.
22-Jul-2019	UAE; 19UK002286; -; United Kingdom	Species: Canine Breed: German Shepherd Dog Sex: U Sex qualifier: Unknown Age: - Weight: 40 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, Otto a German Shepherd dog, weighing 40 kg (signalment otherwise unknown), was treated with FRONTLINE PLUS SPOT ON DOG XL (batch number: R60718, expiry date: FEB 2020), details unknown, by the animal owner for an unknown indication on an unknown date. The owner reported that they live in a rural environment with a high tick burden. The owner was happy that it still stops fleas. The owner reported that it had no effect on ticks. The owner reported finding 20 ticks or more in the first 2 weeks, this time they have counted. They reported that they got the FRONTLINE at a large online pet store. The owner reported that the ticks were filling with blood, hard to say if attached more or less than 48 hours. The owner reported that they take off as soon as they find one and that they are still alive when

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 166 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00173

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											removed. The owner found 1 that had dropped off. Start date of event added for submission purposes only.
22-Jul-2019	UAE; 19UK002288; -; United Kingdom	Species: Canine Breed: West Highland White Sex: F Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	Jun-2019*	Jun-2019*	N/A	D-D	As reported by the animal owner, a West Highland Terrier dog (signalment otherwise unknown) was treated with FRONTLINE PLUS SPOT ON DOG S (batch number and expiry date unknown), details unknown, by the dog's owner in June this year as a prophylactic treatment for fleas. The owner reported that they had bought the FRONTLINE PLUS from a large supermarket for their dog. They reported that it is in date as they were sure to check this on the day of purchase and was the correct dosage for her size and weight. Since then they have had to use two treatments as it did not work and they have had to resort to bathing their pet. The owner reported it is now 3 weeks until they have to use the treatment to protect their dog against fleas and yet again they are having to bath her again as she has got so many fleas it is hard to count how many. The owner is very unhappy with the product as it is supposed to protect against this happening as long as they keep up with the treatments which they have.
22-Jul-2019	UAE; 19UK002301; -; United Kingdom	Species: Canine Breed: Retriever Labrador Sex: F Sex qualifier: Neutered Age: 10.00 Year(s) Weight: 27 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON; FRONTLINE PETCARE HOME AND ENVIRONMENT FLEA SPRAY; Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	16-Jul-2019	19-Jul-2019*	3 Day(s)	D-D	As reported by the animal owner, Saffron, a 10 year old Labrador retriever, weighing 27 kg and of good health, was treated with FRONTLINE SPOT ON DOG L (batch number: 921403AL, expiry date: SEP 2021), administered topically to the back of the neck by the animal owner on 16 JUL 2019 for use as a parasiticide. The owner reported that they had a flea problem last year around JUN 2018. They reported that they called and spoke to someone and that the situation got better by OCT 2018. They were using FRONTLINE PLUS SPOT ON DOG L and FRONTLINE PETCARE HOMEGARD HOUSEHOLD FLEA SPRAY that BI sent. Last week they noticed a mild infestation on the dog so purchased FRONTLINE SPOT ON. By Sunday (21 JUL 2019) the fleas had gone mad. The owner reported that they groom the dog every 3 days and got around 20 fleas off her today (22 JUL 2019). They reported that the dog's skin seems to be getting sore due to the brushing. The owner reported that they have to confess thought it was applied every 3 months so she hasn't had it for a while and its been so warm. They also reported that they have a family of foxes in the garden and the dog likes to sleep where they go. The owner has had 1 bite on leg. The fleas that are being seen can't seem to jump and are easy to catch. The owner reported that they have used HOMEGARD only on the patches the dog sleeps.
22-Jul-2019	UAE; 19UK002303; Devon; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: 4.00 Week(s) Weight: 0.5 kg	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: No (Overdose)	2019*	2019*	N/A	D-C	As reported by a Healthcare professional (Vet, Vet Nurse, Doctor), a 4 to 5 week old cat, weighing 0.5 kg (signalment otherwise unknown), was treated with FRONTLINE SPOT ON CAT, details unknown, by an unknown individual, on an unknown date for an unknown indication. The reporter stated that FRONTLINE SPOT ON used on kitten under 0.5 kg 4-5 weeks old. The kitten is now salivating and has diarrhoea and is vomiting. Start date of event added for submission purposes only.
22-Jul-2019	UAE; 19UK002304; -; United Kingdom	Species: Feline Breed: Feline various breeds	2	2	0	Product used: FIPRONIL SPOT ON CAT	N/A	Jul-2019*	N/A	D-D	As reported by the animal owner, 2 cats, 1 long haired and 1 short haired (signalment otherwise unknown), were treated with FRONTLINE SPOT ON CAT (batch number and expiry date

N/A signifies the information for this field is either not available or not applicable

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

Report printed on 25-Oct-2019 at 8:39:59PM

*indicates Approximate date or weight

Page 167 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00174

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex: U Sex qualifier: Unknown Age: - Weight: Unknown				Other products used: Bob Martins Flea Spray; Route: unknown Was the product used ok?: Unknown to Company					unknown), details unknown, by the neighbour of the animal owner on an unknown date for an unknown indication. The reporter stated that they had used flea spray, Bob Martin before and wondered if that could effect the FRONTLINE. The neighbour reported that the FRONTLINE hadn't killed the fleas and the owners are still seeing them on the short haired cat, however the neighbour had not seen fleas them self. The house has been treated with an unknown product. The neighbour also reported that the cats do come into their house too and that they are going to go get a house spray. Start date of event added for submission purposes only.
22-Jul-2019	UAE; 19UK002308; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	15-Jul-2019*	22-Jul-2019	1 Week(s)	D-D	As reported by the animal owner, 2 cats (signalment otherwise unknown), were treated with FRONTLINE (estimated as FRONTLINE SPOT ON CAT), batch number and expiry date unknown, details unknown, by the animal owner for an unknown indication, estimated to be on 15 JUL 2019. The owner reported that they fleed both cats last week and found fleas again. The owner asked whether they can use FRONTLINE again this soon. The owner reported that the house had been done as well.
22-Jul-2019	UAE; 19UK002310; -; United Kingdom	Species: Canine Breed: Pug Sex: F Sex qualifier: Neutered Age: middle aged Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	08-Jul-2019	08-Jul-2019	0 Day(s)	D-D	As reported by the animal owner, Bonnie and Molly, 2 middle aged, neutered female, Pug cross Cocker Spaniel dogs of good health (signalment otherwise unknown) were treated with FRONTLINE PLUS (estimated as FRONTLINE PLUS SPOT ON DOG M), batch number and expiry date unknown, details unknown, by the animal owner on 08 JUL 2019 as a preventative treatment but they did see a couple of fleas. The owner reported that they had given the dogs FRONTLINE PLUS the previous year but not this year. The owner reported that they purchased via a large online retailer this time and has thrown out the remaining pipettes as it's absolutely useless and not working whatsoever. The owner is going to go back and use Advocate because that works. The owner reported that if anything the product has made the flea issue worse - the fleas are hyper. The owner was unable to provide the batch number or any purchase details as thrown everything out.
22-Jul-2019	UAE; 19UK002311; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL SPOT ON CAT Other products used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON; Route: unknown Was the product used ok?: Unknown to Company	N/A	Jun-2019*	N/A	D-D	As reported by the animal owner, 2 cats (signalment otherwise unknown) were treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), details unknown, by the animal's owner in June and July 2019 for an unknown indication. The owner reported that they have been a regular user of FRONTLINE for their 2 cats and 2 dogs for a number of years. The owner changed to FRONTLINE PLUS when it was introduced as the standard product was becoming less effective. The owner reported that they live in a rural location and the animals through self hunting invariably pick up fleas. They reported that unfortunately the last 2 applications JUN 2019 and JUL 2019 of FRONTLINE PLUS has been totally ineffective and the volume of fleas has been vast. The owner therefore resorted to buying a product from their vet which has worked. The owner also wished to mention that they have also defleed their house with Indorex. The owner is very unhappy about a product which is proving completely ineffective and they feel unable to use the product in the future. This case is linked to case 19UK002312.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 168 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00175

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
22-Jul-2019	UAE; 19UK002312; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL SPOT ON DOG Other products used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON; Indorex; Route: unknown Was the product used ok?: Unknown to Company	N/A	Jun-2019*	N/A	D-D	As reported by the animal owner, 2 dogs (signalment otherwise unknown) were treated with FRONTLINE PLUS (estimated as FRONTLINE PLUS SPOT ON DOG M, batch number and expiry date unknown), details unknown, by the animal's owner in June and July 2019 for an unknown indication. The owner reported that they have been a regular user of FRONTLINE (estimated as FRONTLINE SPOT ON DOG M) for their 2 cats and 2 dogs for a number of years. The owner changed to FRONTLINE PLUS when it was introduced as the standard product was becoming less effective. The owner reported that they live in a rural location and the animals through hunting invariably pick up fleas. They reported that unfortunately the last 2 applications JUN 2019 and JUL 2019 of FRONTLINE PLUS has been totally ineffective and the volume of fleas has been vast. The owner therefore resorted to buying a product from their vet which has worked. The owner had also defleed their house with Indorex. The owner is very unhappy and they feel unable to use the product in the future. This case is linked to case 19UK002311.
23-Jul-2019	UAE; 19UK002313; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	16-Jul-2019	23-Jul-2019*	1 Week(s)	D-D	As reported by the animal owner, a dog (signalment otherwise unknown) was treated with FRONTLINE SPOT ON DOG (estimated as FRONTLINE SPOT ON DOG M), batch number and expiry date unknown, details unknown, by the animal owner a week ago (estimated as 16 JUL 2019) for an unknown indication. The owner reported that the spot on is not working at all. The owner put it on a week ago and the dog still has fleas. On 24 JUL 2019 the owner reported they are hoping they have sorted the problem.
23-Jul-2019	UAE; 19UK002323; -; United Kingdom	Species: Canine Breed: Boxer Sex: F Sex qualifier: Unknown Age: 1.00 Year(s) Weight: 23 kg	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: FIPRONIL SPOT ON DOG; SureKills; Route: Topical / Cutaneous Was the product used ok?: Yes	N/A	22-Jul-2019	8 Day(s)	D-D	As reported by the animal owner, Maggie, a 5 year old female boxer dog, weighing 23 kg and of good health (signalment otherwise unknown), and Peggie, a 1 year old female boxer dog, weighing 23 kg and of good health (signalment otherwise unknown), were treated with FRONTLINE PLUS SPOT ON DOG L (batch number and expiry date unknown) and FRONTLINE SPOT ON DOG L (batch number and expiry date unknown), both correctly administered topically to the back of the neck, every 4 weeks, by the animal owner with the last application 9 days ago (14 JUL 2019) as a prophylactic flea treatment. The animal owner reported that they applied FRONTLINE to the dogs (one has the plus and the other has Spot On) 9 days ago, previous to this every 4 weeks, seeing fleas. The owner took off 10 live fleas yesterday and reported that no one in the house is being bitten. The owner has sprayed the house with SureKills, has been vacuuming everywhere and washed bedding.
23-Jul-2019	UAE; 19UK002324; -; United Kingdom	Species: Canine Breed: Canine various breeds Sex: F Sex qualifier: Unknown Age: - Weight: 28 kg	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: Advocate; Indorex; RIP flea spray; Route: unknown	20-Jul-2019	20-Jul-2019*	0 Day(s)	D-D	As reported by the animal owner, Ellis, a female golden retriever weighing 28 kg (signalment otherwise unknown) and Berry, a female Flat Coat Retriever also weighing 28 kg (signalment otherwise unknown) were treated with FRONTLINE PLUS SPOT ON DOG L (batch number and expiry date unknown) details unknown, by the animal owner on 20 JUL 2019 for an unknown indication. The owner reported that they were on monthly treatment of Advocate and after 3 weeks they had quite a bad infestation of fleas. A friend of the owner recommended FRONTLINE PLUS. The owner used an insecticidal shampoo before FRONTLINE PLUS application and 2 days after application used a normal shampoo.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 169 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00176

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Was the product used ok?: Unknown to Company					The owner also sprayed the house with Indorex and RIP Flea Spray. The owner went through with a flea comb and they are still quite badly infested, with 10 fleas on the Golden retriever and 30+ on the Flat Coat. The owner reported that no one at home was being bitten and that the dogs stay on tiled area. The owner lives in a rural area, walks in woods, and there are hundreds of Rabbits around. The owner has a paddock too. Clinical sign start date added for submission purposes only.
23-Jul-2019	UAE; 19UK002328; -; United Kingdom	Species: Canine Breed: Canine Other Sex: X Sex qualifier: Unknown Age: 4.00 Year(s) Weight: 42 - 44 kg	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Others)	N/A	20-Jul-2019*	0 Day(s)	D-D	As reported by an external customer service advisor and the animal owner, Sky, a 5 year old female Husky dog, weighing 44 kg, health status unknown, and Thunder, a 4 year old male Husky dog, weighing 42 kg, health status unknown, were treated with FRONTLINE PLUS SPOT ON DOG XL (batch number: R6150AR, expiry date: JUN 2020), administered in between the dogs shoulder blades and on their lower backs, by the animal owner on 20 JUL 2019 for an unknown indication. The customer service advisor first reported that a customer of theirs had reported a possible lack of efficacy with some FRONTLINE PLUS and that the customer advised that when applied the product did not smell like it normally does. The animal owner then reported that the first two pipettes worked on their two dogs, they put the second on the dogs on Saturday 20 JUL 2019. They reported that their dogs are still scratching and chewing themselves, also there didn't seem to be any odour when they applied it so they opened one of the last two and couldn't smell anything so they thought this must be a faulty batch. The owner then reported that they treat the dogs all year round, applying the FRONTLINE last on 20 APR 2019, 19 MAY 2019, 22 JUN 2019, and 20 JUL 2019. They reported that they started using pipettes from batch R6150AR on 22 JUN 2019. They also reported that their pets spend time indoors and outdoors and are never bathed or go swimming. The owner clarified that they haven't seen fleas but there is flea dirt/evidence of fleas in their dog's fur. The owner has lived in their house for more than a year and reported that they have treated their house with an environmental flea spray, washed their pets bedding at over 60 degrees Celsius and regularly vacuum all areas that the pets can access. UPDATE 06 AUG 2019: Batch number confirmed at R61508AR expiry JUN 2020. On 29 AUG 2019 QA results were received. Investigation completed for FIPRONIL 10%/S METHOPRENE 9% SPOT ON Lot R61508AR, expiry 2020-06-30. Case
25-Jul-2019	UAE; 19UK002338; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, approximately 2 dogs (signalment otherwise unknown), were treated with FRONTLINE SPOT ON (estimated as FRONTLINE SPOT ON DOG M), batch number and expiry date unknown, details unknown, by the animal owner, on an unknown date for an unknown indication. The owner reported that they put FRONTLINE SPOT ON on their dogs last weekend and he can still see fleas on the dogs. The owner also thinks his house wasn't treated properly, and confirmed he has a home infestation. The owner reported that the FRONTLINE isn't doing what it should do and keeping the fleas away from the dogs. Start date of event added for submission purposes only.
26-Jul-2019	UAE; 19UK002348; -; United Kingdom	Species: Feline Breed: Feline (unknown)	2	2	0	Product used: FIPRONIL 10%/S	N/A	Jul-2019*	19 Day(s)	D-D	As reported by the animal owner, 2 cats in good health (signalment otherwise unknown), were treated with FRONTLINE PLUS SPOT ON CATS (batch number: S41113AW, expiry date: AUG 2021),

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 170 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00177

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex: U Sex qualifier: Unknown Age: - Weight: Unknown				METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes					correctly administered topically to the back of the neck, by the animal owner, every 4 weeks religiously without gaps all year round, with the last application 2 weeks ago (estimated as 12 JUL 2019). The animal owner reported that they still have a flea infestation. The owner has treated the house and bedding etc. and reported that they have loads of flea bites 40-50 bites. Clinical sign start date added for submission purposes only.
26-Jul-2019	UAE; 19UK002352; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: FIPRONIL SPOT ON CAT; Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a cat (signalment otherwise unknown), was treated with FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON CAT), batch number and expiry date unknown, details unknown, by the animal owner, on an unknown date, for an unknown indication. The owner reported that they have used FRONTLINE (assumed FRONTLINE SPOT ON CAT) for years, but stopped for a while due to it becoming no longer effective and started again when FRONTLINE PLUS became available. The owner stated that the last 2 batches of FRONTLINE they had purchased and used have failed to do what they are meant to do, and that their poor cat has caught fleas, and even following full house application and fresh application. The FRONTLINE is just proving very ineffective. The owner reported that maybe for FRONTLINE PLUS those pesky fleas are just bothered by the old formula. Start date of event added for submission purposes only.
26-Jul-2019	UAE; 19UK002359; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	3	3	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: FRONTLINE PETCARE HOME AND ENVIRONMENT FLEA SPRAY; Route: unknown Was the product used ok?: Unknown to Company	26-Apr-2019*	Jul-2019*	5 Day(s)	D-D	As reported by the animal owner, 3 cats (signalment otherwise unknown), were treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), details unknown, by the animal owner for the last 3 months, for an unknown indication. The owner reported that they have 3 cats who have recently developed fleas and that they were advised to use FRONTLINE PLUS as this would protect their home too. The owner has now used all 3 months pipettes and their cats are still scratching. The owner reported that they also meticulously treated their home with the FRONTLINE HOME SPRAY (FRONTLINE PETCARE HOMEGARD HOUSEHOLD FLEA SPRAY), moved furniture and hoovered skirting boards and yet the owner and their daughter have still sustained flea bites.
27-Jul-2019	UAE; 19UK002361; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: M Sex qualifier: Unknown Age: 5.00 Year(s) Weight: 5 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: FRONTLINE PETCARE HOME AND ENVIRONMENT FLEA SPRAY;	N/A	Jul-2019*	4 Day(s)	D-D	As reported by the animal owner, Perry a male cat aged 5 years and weighing 5 kg (signalment otherwise unknown), was treated with FRONTLINE PLUS SPOT ON CATS (batch number S41113AW expiry date AUG 2021), topically to the back of the neck and in between the shoulder blades by the animal owner on 01 JUL 2019, 04 JUL 2019, 27 JUL 2019 and 10 JUN 2019 as a parasiticide. The animal owner reported that they noticed flea bites on their ankles in JUL 2019 then fleas became visible around the home, but they only saw up to 5 but decided to take the following action as they have children in the home. They put FRONTLINE PLUS on their cat on the above dates, and although advised to do it just once they continued to find live fleas on him after brushing

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 171 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00178

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)					daily. They applied it following advice on the web site. The owner also sprayed their home with FRONTLINE HOMEGARD over 01 JUL 2019 to 02 JUL 2019 using 2 full size cans. Since then the owner has hoovered daily as advised then reduced to every second day. The cat also now wears a flea collar and his bedding has been washed at 60 degrees on 3 occasions since they sprayed. The cat hasn't been allowed in the main living areas. The owner also bought a flea lamp but have caught only one with it. The owner reported that they continue to find fleas, for example 2 on the owner's arms on Thursday evening and one on the back of their toddler's neck this morning. The owner brushed the cat last night and discovered a flea which is why they reapplied the FRONTLINE again today. The cat is treated with the product monthly and this continues year-round. The animal owner first noticed the fleas in JUN 2019 as they found bite marks on themselves and identified the fleas from the cat via a comb in JUL 2019. People in the home are being bitten by fleas, the cat is an indoor and outdoor cat, only one animal is in the house, the animal owner sees occasional fleas, the cat is never bathed and never goes swimming, the animal owners have lived in their
27-Jul-2019	UAE; 19UK002363; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: elderly Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	23-Jul-2019	27-Jul-2019	4 Day(s)	D-D	As reported by the animal owner, 2 cats (signalment otherwise unknown), were treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), administered topically to the back of the neck, by the animal owner on 23 JUL 2019 as a parasiticide. The owner reported that as per instructions, they applied FRONTLINE PLUS to each of their 2 cat's necks on Tuesday (23 JUL 2019) afternoon. As of today (27 JUL 2019), both cats are still infested with fleas, with absolutely no sign of any dead or dying, as they have previously witnessed during early treatment. The owner reported that not only have they put both their elderly cats at risk with ineffective chemicals, they now have to subject them to a veterinarian visit to get a treatment that will work. The owner wished to clarify that their cats came with them to the UK a year ago, having lived in Australia flea free for several years previously. The cats have never been treated with FRONTLINE before and all previous similar treatments have had immediate success.
27-Jul-2019	UAE; 19UK002364; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	Jul-2019*	N/A	D-D	As reported by the animal owner, a male dog (signalment otherwise unknown), was treated with FRONTLINE PLUS (estimated as FRONTLINE PLUS SPOT ON DOG M), details unknown, by the animal owner, on an unknown date, for an unknown indication. The owner reported that their dog currently has fleas and they are already using FRONTLINE PLUS to treat him. The owner also got some Beaphar Dog Flea Shampoo which contains Pyrethrum extract and Piperonyl Butoxide, and the shampoo says it can be used every 7 days. The owner was unsure whether they could use the FRONTLINE PLUS and the shampoo at the same time. Start date of event added for submission purposes only.
29-Jul-2019	UAE; 19UK002367; -; United Kingdom	Species: Canine Breed: Poodle (Miniature) Sex: U Sex qualifier: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products	N/A	2019*	N/A	D-D	As reported by the animal owner, two 11 month old Miniature Poodles, weighing 7 kg and 11 kg (signalment otherwise unknown), were treated with FRONTLINE PLUS SPOT ON DOG S (batch number and expiry date unknown, product unsubstantiated), on 2 occasions, the first application being by the dog trimmer and the second by the animal owner, on an unknown date, for an

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
 Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
 *indicates Approximate date or weight

Page 172 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00179

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: 11.00 Month(s) Weight: 7 - 10 kg				used: no other products Route: unknown Was the product used ok?: Unknown to Company					unknown indication. The owner reported that they have just applied the second application of FRONTLINE PLUS (assumed S), but it has not got rid of the fleas on either dog. The owner can see them running around on the skin on the dogs tummies. The owner reported that they have used FRONTLINE on every dog they have ever had with excellent results and wondered if it is at all possible it could be a bad batch. Start date of event added for submission purposes only.
28-Jul-2019	UAE; 19UK002369; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner via Social Media, approximately 2 felines (signalment otherwise unknown) were administered FRONTLINE (assumed FRONTLINE SPOT ON CAT) (batch and expiry unknown, details unknown) for an unknown indication. The animal owner reports that they have spent loads of money on this stuff for cats and it is a waste of money. It doesn't work and Advantage is loads better. Start date added for submission purposes only.
29-Jul-2019	UAE; 19UK002375; -; United Kingdom	Species: Canine Breed: Terrier (Jack Russell) Sex: M Sex qualifier: - Age: 8.00 Year(s) Weight: 13 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	N/A	15-Jul-2019	5 Day(s)	D-D	Product applied on 10 of July and on 15 still got live fleas on dog. Owner not found any dead fleas but says more live fleas than previously.
29-Jul-2019	UAE; 19UK002376; -; United Kingdom	Species: Canine Breed: Canine various breeds Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	7	7	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	22-Jul-2019	0 Day(s)	D-D	As reported by the animal owner, seven canines, six little dogs and one Rottweiler (signalment otherwise unknown) were administered FRONTLINE SPOT ON (assumed FRONTLINE SPOT ON DOG M, batch, expiry and further details unknown) 7 days ago (22 JUL 2019) for fleas. The animal owner has been ill and so unable to go to the vets to purchase the normal flea product that is used on the animals. Their granddaughter recommended to purchase FRONTLINE SPOT ON online and get it sent to them. They applied the product 7 days ago and are seeing fleas on all the dogs. They are not seeing loads, about 3 fleas on each dog. They are extremely disappointed with the product as it is supposed to stop fleas. The animal owner will not be using FRONTLINE again and if friends ask about it, will not be recommending it.
29-Jul-2019	UAE; 19UK002377; Lincolnshire; United Kingdom	Species: Feline Breed: Feline various breeds Sex: M Sex qualifier: Neutered Age: 7.00 Year(s) Weight: 4 kg*	3	3	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: FIPRONIL SPOT ON CAT;	May-2019*	Jul-2019*	8 Week(s) 5 Day(s)	D-D	As reported by the animal owner, Coco a 15 year old British Short Hair, Howel a 9 year old Domestic Short Hair and Milo a 7 year old Bengal cross, all male neutered felines, all weighing approximately 4 kg and in good condition, were administered FRONTLINE PLUS SPOT ON CAT (batch R40718AW expiry JUN 2020) topically to an unknown site, by the animal owner, at an unknown dose, monthly from MAY 2019 as a preventative. The animal owner has previously used FRONTLINE SPOT ON. The product was purchased at a supermarket. They have never suffered with fleas

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 173 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00180

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Route: Topical / Cutaneous Was the product used ok?: Yes					and now have fleas. They are very disappointed as their pets have never had fleas and since using this product, they all have fleas. The animal owner also has three dogs (linked cases).
29-Jul-2019	UAE; 19UK002378; Lincolnshire; United Kingdom	Species: Canine Breed: Poodle (Toy) Sex: F Sex qualifier: Neutered Age: 4.50 Year(s) Weight: 8 kg	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: FIPRONIL SPOT ON DOG; Route: Topical / Cutaneous Was the product used ok?: Yes	May-2019*	May-2019*	0 Day(s)	D-D	As reported by the animal owner, Boo a 5 year old, and Lola a 4.5 year old, both female neutered Poodle cross canines, weighing 8 kg and in unknown condition, were administered FRONTLINE PLUS SPOT ON DOG S (batch S61716AL expiry JUN 2021) topically to an unknown site, by the animal owner, at an unknown dose, in MAY 2019 as a preventative. The animal owner has previously used FRONTLINE SPOT ON. The product was purchased at a supermarket. They have never suffered with fleas and now have fleas. They are very disappointed as their pets have never had fleas and since using this product, they all have fleas. The animal owner also has three cats and one other dog (linked cases).
29-Jul-2019	UAE; 19UK002379; Lincolnshire; United Kingdom	Species: Canine Breed: Poodle (Toy) Sex: F Sex qualifier: Neutered Age: 3.50 Year(s) Weight: 15 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: FIPRONIL SPOT ON DOG; Route: Topical / Cutaneous Was the product used ok?: Yes	May-2019*	Jul-2019*	N/A	D-D	As reported by the animal owner, Honey, a 3.5 year old female neutered Poodle cross canine, weighing 15 kg and in unknown condition, was administered FRONTLINE PLUS SPOT ON DOG M (batch S62703AW expiry SEP 2021) topically to an unknown site, by the animal owner, at an unknown dose, in MAY 2019 as a preventative. The animal owner has previously used FRONTLINE SPOT ON. The product was purchased at a supermarket. They have never suffered with fleas and now (as of early JUL 2019) have fleas. They are very disappointed as their pets have never had fleas and since using this product, they all have fleas. The animal owner also has two other dogs and three cats (linked cases).
29-Jul-2019	UAE; 19UK002380; -, United Kingdom	Species: Feline Breed: Feline (unknown) Sex: F Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	26-Jul-2019	29-Jul-2019	3 Day(s)	D-D	As reported by the animal owner, a neutered female cat (signalment otherwise unknown), was treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), details unknown, by the animal owner on 26 JUL 2019 for an unknown indication. The owner reported that they have both a dog and a cat, and that the dog was groomed on 26 JUL 2019 and the groomer noticed a few fleas on him. The owner then treated their dog and cat with FRONTLINE PLUS the same afternoon, and when the cat went to get spayed on 29 JUL 2019, the vet contacted the owner to say she had some fleas and flea dirt in her fur.
29-Jul-2019	UAE; 19UK002381; -, United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used	2018*	2019*	N/A	D-D	As reported by the animal owner, a dog (signalment otherwise unknown), was treated with FRONTLINE (estimated as FRONTLINE SPOT ON DOG M), batch number and expiry date unknown, details unknown, by the animal owner, for the past year, for an unknown indication. The owner reported that they are unsure if this time they had a bad batch however their dog has fleas. Start date of event added for submission purposes only.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 174 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00181

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						ok?: Unknown to Company					
30-Jul-2019	UAE; 19UK002382; -; United Kingdom	Species: Canine Breed: West Highland White Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a West Highland White Terrier canine (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON DOG M) (batch and expiry unknown) (details unknown) by the animal owner, for an unknown indication. The animal owner reports that they have used the product along with spraying the house and the animal still has fleas. Start date added for submission purposes only.
29-Jul-2019	UAE; 19UK002383; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: X Sex qualifier: Unknown Age: - Weight: 24 - 26 kg	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: FRONTLINE PETCARE HOME AND ENVIRONMENT FLEA SPRAY; Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	15-Jul-2019	15-Jul-2019	0 Day(s)	D-D	As reported by the animal owner, Nikita, a 6 year old, female Siberian Husky dog, weighing 24 kg, health status unknown, and Tyson, a male Staffordshire Bull Terrier, weighing 26 kg, age and health status unknown, were treated with FRONTLINE PLUS SPOT ON DOG L (batch number and expiry date unknown), administered topically to the neck, by the animal owner, on the 15 JUL 2019, for an unknown indication. The owner reported that the solution they purchased has had no effect. They used the FRONTLINE after noticing their current flea issue on 15 JUL 2019. The owner also purchased FRONTLINE PETCARE HOMEGARD HOUSEHOLD FLEA SPRAY. The FRONTLINE PETCARE HOMEGARD HOUSEHOLD FLEA SPRAY was used on 26 JUL 2019. The store assistant also advised the owner that 1 tin of FRONTLINE HOMEGARD would be sufficient for their flat. The owner reported that their 2 bed property is now covered with fleas. The owner reported that they use the products in the summer and only then when they see fleas or when they see their pets itching more than usual. The owner also reported that people in the house are being bitten, that the animals are taken outdoors twice a day and have access to the garden as well as spending time indoors also, that all the animals in the household have been treated with a flea product, and that they are seeing 5 or more fleas on their pets at the same time. The dogs swim once a month, but are not bathed and don't swim within 2 days of product application. The owner has lived in their house for more than a year. The owner has also washed their pets bedding at over 60 degrees Celsius and regularly vacuum all areas the pets can access. Case linked to case 19UK002385.
29-Jul-2019	UAE; 19UK002385; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: X Sex qualifier: Unknown Age: - Weight: 5 - 7.5 kg	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: FRONTLINE PETCARE HOME AND ENVIRONMENT FLEA SPRAY; Route: unknown Was the	15-Jul-2019	15-Jul-2019	0 Day(s)	D-D	As reported by the animal owner, Kruger, a male cat weighing 5 kg (signalment otherwise unknown), and Bella, a female cat weighing 7.5 kg (signalment otherwise unknown) were treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), applied topically to the neck, by the animal owner, on 15 JUL 2019, for an unknown indication. The owner reported that the solution they purchased has had no effect. The owner first noticed their current flea problem on 15 JUL 2019. The owner also purchased FRONTLINE PETCARE HOMEGARD HOUSEHOLD FLEA SPRAY. The store assistant advised the owner that 1 tin of FRONTLINE HOMEGARD would be sufficient for their flat. The owner reported that their 2 bed property is now covered with fleas. The owner reported that they use the products in the summer and only then when they see fleas or when they see their pets itching more than usual. The owner also reported that people in the house

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 175 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00182

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						product used ok?: Unknown to Company					are being bitten, that the animals have access to the garden as well as spend time indoors, that all the animals in the household have been treated with a flea product, and that they are seeing 5 or more fleas on their pets at the same time. The owner has lived in their house for more than a year. The owner has also washed their pets bedding at over 60 degrees Celsius and regularly vacuum all areas the pets can access. Case linked to case 19UK002383.
30-Jul-2019	UAE; 19UK002387; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: F Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a female dog (signalment otherwise unknown), was treated with FRONTLINE SPOT ON DOG S (batch number and expiry date unknown), details unknown, by the animal owner, on an unknown date, for an unknown indication. The owner reported that the FRONTLINE has been unsuccessful every time they have used it, and the dog has also been to the vet and again has been recommended to use FRONTLINE. The owner has spent a great deal of money without any results. The owner reported that they have the last FRONTLINE packet but all the others went in the bin. Start date of event added for submission purposes only.
27-Jul-2019	UAE; 19UK002393; -; United Kingdom	Species: Canine Breed: Spaniel (English Springer) Sex: F Sex qualifier: Unknown Age: 11.00 Year(s) Weight: 15 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: FRONTLINE PETCARE HOME AND ENVIRONMENT FLEA SPRAY; Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	Mar-2019*	Jun-2019*	N/A	D-D	As reported by the animal owner, Molly, an 11 year old female English Springer Spaniel, weighing 15 kg and of unknown reproductive status and health, was treated with FRONTLINE PLUS SPOT ON DOG M (batch number: S60424AL, expiry date: JAN 2021), applied topically to the base of the neck near the shoulder blades, by the animal owner, in MAR 2019, JUN 2019 and finally on 23 JUL 2019 as a parasiticide. In JUN 2019 the owner reported that they noticed fleas on their dog and that each day they are getting at least 10 fleas off the dog with the comb. The owner reported that they use FRONTLINE PLUS all year round but only when they see fleas, but as soon as they spot a flea they have the FRONTLINE available. The owner treated the dog, she continued to have fleas throughout the month and the owner treated her for a second time after 30 days. The owner along with applying the FRONTLINE also steamed each room in the house and the car as well as washing all the soft furnishings and bedding at 60 degrees Celsius plus, and twice using FRONTLINE PETCARE HOMEGARD HOUSEHOLD FLEA SPRAY in each room (3 bottles used in total) on 3 separate occasions. The owner has also been vacuuming twice a day, each day and twice a day they use a flea comb to go over their dog, drowning the fleas in hot soapy water. The dog has been weighed so the owner purchased the correct dosage of product and the dog has remained dry each time for 3 days after application of the product. The owner also reported that people in the home are being bitten by fleas, that the dog spends time outdoors and indoors and that all animals in their household and all in contact animals have been treated with a flea product. The dog is bathed or goes swimming no more than once a week and the owner has lived in their house for more than a year. The owner then stated that they have been doing all the recommended advice for nearly 2 months and have seen zero reduction of fleas. The owner reported that on 29 JUL 2019 they treated
30-Jul-2019	UAE; 19UK002394; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier:	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON	08-Jun-2019	30-Jul-2019	22 Day(s)	D-D	As reported by the animal owner, a cat (signalment otherwise unknown), was treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), applied by the cat's owner on 08 JUN 2019 and 08 JUL 2019 as the cat had fleas. The owner reported on 30 JUL 2019 that the cat still had fleas, the

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 176 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00183

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Unknown Age: - Weight: Unknown				Other products used: House Flea Treatment; Route: Topical / Cutaneous Was the product used ok?: Unknown to Company					owner was seeing a couple of fleas when the cat was combed, but the owner was not being bitten. The owner did not have any other animals. The owner reported that other cats visited the garden and one had recently been in the house. The house was treated a while ago.
30-Jul-2019	UAE; 19UK002395; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	3	3	0	Product used: FIPRONIL SPOT ON CAT Other products used: FRONTLINE PETCARE HOME AND ENVIRONMENT FLEA SPRAY; Route: unknown Was the product used ok?: Unknown to Company	11-Jul-2019*	11-Jul-2019*	0 Day(s)	D-D	As reported by the animal owner, one 21 year old cat and 2 kittens (signalment otherwise unknown), were treated with FRONTLINE SPOT ON CAT (product unsubstantiated), just over 2.5 weeks ago (estimated as 11 JUL 2019), details unknown, by the animal owner, for an unknown indication. The owner reported that they recently welcomed the two kittens and that they already had the 21 year old cat. Due to the fact that its summer and their older cat likes being outside, the owner bought FRONTLINE and treated all 3 animals. The owner had noticed that one of the kittens had started with fleas but was assured in a large pet shop that the product would kill them off very quickly. The owner also bought FRONTLINE PETCARE HOMEGARD HOUSEHOLD FLEA SPRAY for the home and did all of it and a week later they did it all again. The owner reported that they just checked the kittens and the flea infestation was so bad that they have had to bathe them to get them off. The owner reported that both kittens are crawling with fleas and this is just over 2.5 weeks after the initial treatment. The fleas that came off were a mixture of very small and large adults. The owner's son is being bitten so badly that they are going to have to take him to the doctors. The owner stated that the situation if anything has got far worse.
30-Jul-2019	UAE; 19UK002396; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a male cat (signalment otherwise unknown), was treated with a FRONTLINE PRODUCT (estimated as FRONTLINE SPOT ON CAT), details unknown, 3 times, by the animal owner, for an unknown indication. The owner reported that they were concerned that the product wasn't working whatsoever, they have treated the cat 3 times and there are still fleas which are seemingly getting worse. The owner fears that this is making him and his partner ill now and they just cant cope any more (further follow up was attempted but was not possible). The owner reported that its as if the fleas have become immune to the product. Start date of event added for submission purposes only.
30-Jul-2019	UAE; 19UK002398; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL SPOT ON CAT Other products used: Unspecified House flea product; Route: unknown Was the product used ok?: No (Overdose)	N/A	Jul-2019*	0 Day(s)	D-D	As reported by the animal owner, their 2 cats (signalment otherwise unknown) were treated with FRONTLINE (assumed to be FRONTLINE SPOT ON CAT) batch number and expiry date unknown, route and frequency unknown, administered by the cat's owner last week (the owner reported that they had used all 6 pipettes on both the cats). The owner reported that they found the product completely ineffective in combating fleas from their home, they had washed all the cats bedding, the sofa and then had treated the whole house only to find the cats still had fleas. No further information was supplied. Date of adverse event added for submission purposes only.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 177 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00184

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
30-Jul-2019	UAE; 19UK002400; -; United Kingdom	Species: Canine Breed: German Shepherd Dog Sex: F Sex qualifier: Neutered Age: 3.00 Year(s) Weight: 31.5 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Overdose)	Jul-2019*	Jul-2019*	0 Day(s)	D-C	As reported by the trainee veterinary nurse, Kelly, a 3 year old neutered female German Shepherd Dog, weighing 31.5 kg and of good health, was treated with FRONTLINE SPOT ON DOG L (batch number: S21216AX, expiry date: AUG 2021), administered topically to the back of the neck by the animal owner, on 2 occasions in JUL 2019 for an unknown indication. The vet nurse reported that the dog was treated with FRONTLINE, with 1 pipette given one day and two days later another was administered by the animal owner again. On the day after the dog had the second pipette it had some blood in its urine. No treatment has been received yet, however the dog is coming into the practice today (30 JUL 2019) for treatment/examination.
30-Jul-2019	UAE; 19UK002402; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: F Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	30-Jul-2019*	11 Day(s)	D-D	As reported by the animal owner, a cat (signalment otherwise unknown), was treated with FRONTLINE SPOT ON CAT (batch number and expiry date unknown), details unknown, by the animal owner, 11 days ago (19 JUL 2019), for an unknown indication. The owner reported that the have found a couple of fleas on the cat and they think they are from the garden.
31-Jul-2019	UAE; 19UK002404; -; United Kingdom	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: X Sex qualifier: Neutered Age: 13.00 Year(s) Weight: 4.5 kg	4	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: FIPRONIL SPOT ON CAT; Route: Topical / Cutaneous Was the product used ok?: Yes	Jul-2018*	25-Jul-2019	2 Day(s)	D-D	As reported by the animal owner, 4 cats, one 13 year old neutered male Domestic Shorthair cat (Steve), weighing 4.5 kg and with a flea allergy, one 14 year old neutered female Domestic Shorthair cat (Tilly), weighing 4.5 kg and of unknown health status, and 2 others of unknown signalment, were treated with FRONTLINE PLUS SPOT ON CAT (batch number :S41113AW, expiry date: AUG 2021), correctly administered topically to the back of the neck, every 4 weeks for the past year, last application on 23 JUL 2019, for an unknown indication. The owner started to notice the fleas a couple of days after applying the FRONTLINE PLUS. Before FRONTLINE PLUS the cats were treated with FRONTLINE SPOT ON, and after the last application 2 of the cats are fine but 2 have fleas (Steve and Tilly), roughly 3 on them each day with the owner being able to catch the fleas easily. The owner is not being bitten and is spraying the house with RIP, vacuuming and washing all bedding at 60 degrees.
31-Jul-2019	UAE; 19UK002411; -; United Kingdom	Species: Feline Breed: Feline Other Sex: F Sex qualifier: Unknown Age: 6.00 Month(s) Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: Indorex; Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	07-May-2019	28-Jul-2019	0 Day(s)	D-D	As reported by the animal owner, Nola, an 8 year old, domestic female cat, described as skinny (signalment otherwise unknown), and Ripley, a 6 month old, domestic female kitten (signalment otherwise unknown), were treated with FRONTLINE PLUS SPOT ON CAT (batch number S41303AW, expiry date unknown), applied topically to the back of the neck, by the animal owner, every 4 weeks with the last application on 28 JUL 2019, for an unknown indication. The owner reported that their indoor cat picked up fleas at a vets visit despite being treated with FRONTLINE. The owner reported that they had used FRONTLINE on 7 MAY 2019, 7 JUN 2019, 7 JUL 2019, and 28 JUL 2019 after first noticing their current issue 4 days ago, the same day that they applied the most recent dose of FRONTLINE, and they are still combing fleas from her indoor cat's fur. The owner reported that their house is flea treated with Indorex and so the fleas cannot be living in the house, and they have also not seen a single flea on anywhere but the cat.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 178 of 867

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00185

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											People in the house are not being bitten by fleas, the cats spend time indoors only, all the pets that live in the household have been treated with a flea product, and the owner's cats are never bathed or go swimming. The owner has lived in their house for more than a year and as also washed their pets bedding at over 60 degrees Celsius and regularly vacuumed all areas the cats can access.
31-Jul-2019	UAE; 19UK002419; -; United Kingdom	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: F Sex qualifier: Neutered Age: 9.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	N/A	31-May-2019*	N/A	D-D	As reported by the animal owner, Betty, a 9 year old, neutered female Domestic Shorthair cat, of unknown weight and in good health, was treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), correctly administered topically to the back of the neck, by the animal owner, every 4 weeks for a long time with the last application on 22 JUL 2019, for an unknown indication. The owner reported that they have noticed fleas on the cat for the past 2 months. FRONTLINE usually works fine but hasn't recently and the owner wondered if there is something wrong with the product. The owner has sprayed the house and reported that the cat is scratching loads and chewing the base of its tail a lot. They haven't seen any flea dirt or fleas but the owner's husband grooms the cat and has seen 6 fleas. The cat goes outside a lot and no one in the house is being bitten. UPDATE 30 AUG 2019: QA results received. Investigation completed for FIPRONIL 10%/S METHOPRENE 12% SPOT ON Lot Unknown, expiry . Case investigated by France - Toulouse. Final complaint evaluation An adverse event for FRONTLINE PLUS SPOT ON CATS, batch unknown, was received by BIAH QA on the 09th of August 2019. This is the 41st complaint received for this LOE, in the past 12 months, all batches included. This defect is rare, it represents 0.2 ppm of every batch produced in 2017 (17 complaints for 78 447 597 pipettes) (including all batches of Frontline Regular and Combo for Cats and Dogs/all ranges). The complaint sample is not received and pictures are not attached to this case. Batch record investigation: Batch unknown. Root cause investigation: Stability: during the test of stability, we can observe that one batch out of thirteen an increase in the water content (regular cat). Efficacy, safety and quality of the product not in question because the whole dose is applied. The tests of stability are conform at the specifications. Quality issue: at this day, no knowledge of any known quality
31-Jul-2019	UAE; 19UK002420; -; United Kingdom	Species: Canine Breed: Retriever (Labrador, Chocolate) Sex: U Sex qualifier: Unknown Age: 18.00 Month(s) Weight: 29 kg	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, 2 Chocolate Labrador Retriever dogs, one 11 year old female, weighing 29 kg, of good health, and on Propalin as she had trouble after a spay (signalment otherwise unknown), and one 18 month old, weighing 29 kg also, and of good health (signalment otherwise unknown), were treated with FRONTLINE PLUS SPOT ON DOG L (batch number unknown, expiry date unknown), details unknown, by the animal owner, on an unknown date, for an unknown indication. The owner reported that the dogs are scratching and some fleas have been seen on them. One dog is pulling her fur out, and only 1 or 2 fleas have been seen on the dogs. No one is being bitten in the home, and the owner doesn't feel like there is a home infestation. The owner also has a cat which isn't scratching and no fleas have been seen on him, just the dogs. The owner has treated the house twice just in case. The dogs were taken to the vet who said FRONTLINE doesn't work and their vet just wanted to sell him another flea treatment. The FRONTLINE PLUS was bought at a large pet retailer. Start date of event added for submission purposes only.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 179 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00186

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
31-Jul-2019	UAE; 19UK002421; -; United Kingdom	Species: Feline Breed: Feline various breeds Sex: F Sex qualifier: Unknown Age: 10.00 Year(s) Weight: 7 - 8 lbs	3	3	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	Jan-2018*	Jul-2019*	13 Day(s)	D-D	As reported by the animal owner, May a 10 year old American Shorthair weighing 8 lbs, Lucy a 10 year old American Shorthair weighing 8 lbs and Zena an 11 year old British Shorthair weighing 7 lbs, all female felines (signalment otherwise unknown) were administered FRONTLINE PLUS SPOT ON CAT (batch S49897AW and expiry JUN 2021) topically to the back of the neck by the animal owner, at a dose of 1 dose twice a year in summer and winter for cat fleas. The animal owner reports that it hasn't worked at all. Not a single flea seems to have died. It wasn't a heavy infestation but it is now getting worse, despite combing their cats daily. The product was applied correctly and they have used it in the past. The animal owner states that they are now going to have to try a different brand and that they are unhappy that they have used a toxic product on their pets which hasn't worked, and they are now going to have to use another. The animal owner reports that they last used the product on 18 JUL 2019, JAN 2019, JUN 2018 and JAN 2018. People in the home are being bitten and the animals spend time indoors and outdoors. All animals that live in the household and in contact animals had been treated with a flea product, the animal owner is seeing more than ten fleas at a time when combing and the animals are bathed or go swimming about once a month. The animal owner has treated the home with an environmental flea treatment, washed the pet's bedding at over 60 degrees, regularly vacuumed all areas that the pets can access and also combs the animals daily - but not within three days of applying the FRONTLINE product.
31-Jul-2019	UAE; 19UK002424; West Sussex; United Kingdom	Species: Canine Breed: Retriever Labrador Sex: M Sex qualifier: - Age: 3.00 Year(s) Weight: 32 kg	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	18-Jul-2019	18-Jul-2019	0 Day(s)	D-D	As reported by the animal owner, George, a 3 year old male intact Labrador canine, weighing 32 kg and in unknown condition, and one other Labrador canine (signalment otherwise unknown) were administered FRONTLINE PLUS SPOT ON DOG L (batch S60626AR expiry 01 FEB 2021) topically to an unknown site, by the SQP at an unknown dose, on 18 JUL 2019 for routine prevention. The animal owner reports that the dogs are all scratching a bit and that George is particularly bad. The customer has checked through the coat and found flea dirt at the base of the tail. The house as been sprayed with Ficam w (active ingredient Bendiocalm) and the van has been fogged. The animal owner also has four Spaniels (see linked case).
31-Jul-2019	UAE; 19UK002425; West Sussex; United Kingdom	Species: Canine Breed: Spaniel Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	6	6	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	18-Jul-2019	18-Jul-2019	0 Day(s)	D-D	As reported by the animal owner, six Spaniel canines (signalment otherwise unknown) were administered FRONTLINE PLUS SPOT ON DOG M (batch and expiry unknown) topically to an unknown site, by the SQP at an unknown dose, on 18 JUL 2019 for routine prevention. The animal owner reports that the dogs are all scratching a bit. The house as been sprayed with Ficam w (active ingredient Bendiocalm) and the van has been fogged. The animal owner also has two Labradors (see linked case).
31-Jul-2019	UAE; 19UK002426; South Molton; United Kingdom	Species: Canine Breed: Spaniel Sex: F	2	2	0	Product used: FIPRONIL 10%/S	25-May-2019*	May-2019*	N/A	D-D	As reported by the distributor after a report from the animal owner, Kiki, a 9 year old, female neutered Springer Spaniel dog, weighing 19 kg, health status unknown, and Molly, a 6 year old, neutered female Springer Spaniel dog, weighing 21 kg, health status

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 180 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00187

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: Neutered Age: 6.00 Year(s) Weight: 19 - 21 kg				METHOPRENE 9% SPOT ON Other products used: FIPRONIL SPOT ON DOG; Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)					unknown, were treated with FRONTLINE PLUS SPOT ON DOG L (batch number: S62911AX, expiry date: SEP 2021) administered topically to the back of the neck, by the animal owner on approximately 25 MAY 2019 as a prophylactic treatment. The owner reported to the distributor that prior to FRONTLINE PLUS they had used FRONTLINE SPOT ON DOG L, and that soon after FRONTLINE PLUS application live fleas were seen on both spaniels. The owner contacted their vet who explained how the product worked and suggested to persevere with the product. The owner also treated their house with a fogger and house spray. 7 weeks after the 1st application (estimated as 13 JUL 2019), the owner reapplied the FRONTLINE PLUS and reported that the fleas were still alive and flea dirt could be seen in the dog's coats. Molly was also clipped which exposed flea dirt.
01-Aug-2019	UAE; 19UK002428; Lanarkshire; United Kingdom	Species: Feline Breed: Maine Coon Cat Sex: M Sex qualifier: Neutered Age: 10.00 Year(s) Weight: 4.1 kg	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: FIPRONIL 8.3% / S-METHOPRENE 10% / PRAZQUANTEL 8.3% / EPRINOMECTIN 0.4% SPOT ON; Route: unknown Was the product used ok?: Unknown to Company	N/A	01-Aug-2019*	10 Month(s)	D-D	As reported by the veterinary nurse, Jeremy a male neutered Maine Coon feline born on 01 SEP 2008, weighing 4.1 kg and in good condition, was given BROADLINE SPOT ON SOLUTION FOR CATS 2.5-7.5 KG (batch number CES020AAA expiry date 31 AUG 2020) topically on 16 JUL 2019 to an unknown site at an unknown dose by the animal owner as a parasiticide. The product was recommended to the animal owner by the vet after seeing fleas, and the product has been used on the cat monthly since SEP or OCT 2018. The animal owner was using FRONTLINE SPOT ON CAT (batch and expiry unknown) prior to this. The animal owner is seeing lots of fleas and is getting bitten. They have been using household spray (RIP) as per the instructions. The animal owner is adamant they have applied to product accordingly and therefore believe that BROADLINE isn't working. Start date for submission purposes only.
01-Aug-2019	UAE; 19UK002429; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: F Sex qualifier: Neutered Age: 19.00 Year(s) Weight: 2.75 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: FIPRONIL SPOT ON CAT; Thyronorm; Metacam meloxicam 0.5 mg/ml oral suspension cats guinea pigs; Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination	27-Jun-2019	27-Jun-2019	N/A	D-D	As reported by the animal owner, Poppy, a 19 year old, neutered female Tabby cat (breed unknown), weighing 2.75 kg and of fair health, was treated with FRONTLINE PLUS SPOT ON CAT (batch number: S40711AW, expiry date: MAY 2021), administered topically to the back of the neck, by the animal owner, 2 weeks ago (estimated as 18 JUL 2019) for an unknown indication. The owner reported that they applied FRONTLINE PLUS 2 weeks ago and then 3 weeks before that (27 JUN 2019), and prior to this they were applying normal FRONTLINE SPOT ON CAT. The owner had never had a problem but after applying the first FRONTLINE PLUS noticed fleas. The owner took the cat to the vets as she was scratching a lot and causing scabs. The vet practice advised to apply another FRONTLINE PLUS pipette. The vet saw a few fleas however the owner reported that they are not seeing fleas on the cat, but the cat is scratching a lot so they presume they are on her. The owner also reported that no one in the house is being bitten and that the cat goes outside and a lot of the time goes under bushes where wildlife also go. There is also a Hedgehog that lives in the garden. The cat has hyperthyroidism and so is on Thyronorm and also is on METACAM (assumed METACAM 0.5 MG/ML ORAL SUSPENSION FOR CATS AND GUINEA PIGS, batch number, expiry date and all other details unknown) for arthritis and dental pain.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 181 of 867

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

v1.2

ED_005739D_00014390-00188

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						program not respected)					
01-Aug-2019	UAE; 19UK002430; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	01-Jul-2019*	Jul-2019*	2 Week(s)	D-D	As reported by the animal owner, two felines, Big Boy and Cleo (signalment otherwise unknown) were given FRONTLINE SPOT ON CAT (batch number: S2101YAW, expiry: JUN 2021) administered topically to the head and shoulders, on 15 JUL 2019, 16 JUL 2019, and 17 JUL 2019, by the animal owner, for an unknown indication. The animal owner reports that they followed the instructions on the pack but the product did not make any difference as both cats are still infested. Start date for submission purposes only. The owner first noticed their current flea issue at the end of JUN 2019 and started using the product at the start of JUL 2019 (estimated as 01 JUL 2019). No one in the house is being bitten, the cats go indoors and outdoors, all animals in the household and all in contact animals have been treated with a flea product, and the owner is seeing many fleas-5 or more at the same time on the cats. The cats never go swimming or get bathed, and therefore this does not occur within 2 days of product administration, the owner has lived in their house for more than a year, and they have regularly vacuumed all areas the pets can access, however they have not treated their home with an environmental flea treatment and have not washed their pets bedding at over 60 degrees Celsius.
01-Aug-2019	UAE; 19UK002431; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: FIPRONIL SPOT ON CAT; Route: unknown Was the product used ok?: Unknown to Company	14-Jul-2019*	01-Aug-2019	18 Day(s)	D-D	As reported by the animal owner, approximately 2 cats (signalment unknown), were treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), details unknown, by the animal owner 2.5 weeks ago (estimated as 14 JUL 2019), for an unknown indication. The owner reported that they had always used the FRONTLINE SPOT ON CAT which was always brilliant, but purchased the FRONTLINE PLUS and the cats have still got fleas two and a half weeks after treatment. The owner waited to see if it worked and it doesn't seem to have done anything.
01-Aug-2019	UAE; 19UK002433; Renfrewshire; United Kingdom	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: M Sex qualifier: - Age: 6.00 Week(s) Weight: 0.6 kg	1	1	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: unknown Was the product used ok?: Yes	29-Jul-2019	Jul-2019*	2 Day(s)	D-D	As reported by the attending veterinary surgeon, Buddy, a 6 week old, intact male Domestic Shorthair Kitten, weighing 0.6 kg and of good health, was treated with FRONTLINE SPRAY (batch number: R02810A, expiry date: JUN 2020), details unknown, by the animal owner, for an unknown indication on 29 JUL 2019. The kitten is a new kitten and was in the house for a couple of days before the owner realised the kitten had brought in a heavy flea burden. The kitten was treated with the FRONTLINE SPRAY, with their other cat treated with FRONTLINE SPOT ON CAT routinely. There are lots of live fleas still seen on the kitten but the kitten is in good health otherwise even if a bit thin. The owners have treated the whole house with Indorex. Start date of event added for submission purposes only.
01-Aug-2019	UAE; 19UK002437; -; United Kingdom	Species: Feline Breed: Ragdoll Sex: U Sex qualifier: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON	N/A	31-Jul-2019	0 Day(s)	D-D	As reported by the customer services staff member, Alfie, a Ragdoll feline (signalment otherwise unknown) was administered FRONTLINE PLUS SPOT ON CAT (batch S41002AW expiry JUL 2021, details unknown) by the animal owner on 31 JUL 2019 for an unknown indication. The customer services staff member had a

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 182 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00189

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: - Weight: Unknown				Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company					complaint referring to yellowing of the animal's fur post dose of FRONTLINE PLUS. The customer wants compensation. The animal owner applied the product yesterday (31 JUL 2019) and advised that where the application site as it has turned yellow. UPDATE 29 AUG 2019: QA results received. Investigation completed for FIPRONIL 10%/S METHOPRENE 12% SPOT ON Lot S41002AW, expiry 2021-07-31. Case investigated by France - Toulouse. Final complaint evaluation A product quality complaint for FRONTLINE PLUS SPOT ON CATS, batch number S41002AW, was received by BIAH QA on the 09th of August 2019. The complaint description is: Adverse Event. This is the first complaint regarding this kind of defect for this batch. The complaint sample is not received but the pictures show the defect. The retention sample is not reviewed : it is stored for identification purposes. Therefore, it is not applicable to this kind of defect. Batch record investigation: Bulk batch: S410. Manufacturing date: 14/08/2018. Expiry date: 07/2021. Manufacturing quantity: 999 liters Associated deviation(s): No deviation associated to this batch. Change control associated: This batch was not concerned by any change control. Observation(s): No observation associated to this batch. Results of QC testing: Conform at specifications. All parameters verified during manufacturing of this batch of bulk are conform. Filling batch: S41002. Manufacturing date: 21/08/2018. Expiry date: 07/2021. Manufacturing quantity: 34520 blisters of 3 pipettes. Associated deviation(s): No deviation associated to this batch Change control associated: This batch was not concerned by any change control. Observation(s): One observation is
01-Aug-2019	UAE; 19UK002439; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, Alexander, a male dog (signalment otherwise unknown), was treated with FRONTLINE (estimated as FRONTLINE SPOT ON DOG M), batch number: 03661103048886, expiry date: AUG 2019, details unknown, by the animal owner, on an unknown date, for an unknown indication. The owner reported that they put a second dose of FRONTLINE on the dog 2 months after the last dose, which does not seem to be working and the dog is persistently scratching. On 06 AUG 2019, the owner reported that their dog is still scratching regularly, and that this has never happened before. On 14 AUG 2019, the owner reported that their dog is now scratching himself persistently. Start date of event added for submission purposes only.
01-Aug-2019	UAE; 19UK002440; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a dog (signalment otherwise unknown), was treated with FRONTLINE SPOT ON (estimated as FRONTLINE SPOT ON DOG M), batch number and expiry date unknown, details unknown, by the animal owner, twice, for an unknown indication. The owner reported that it hasn't worked at all either time and that they paid a lot of money for it not work. Start date of event added for submission purposes only.
01-Aug-2019	UAE; 19UK002441; -; United Kingdom	Species: Canine Breed: Spaniel (English Springer)	2	2	0	Product used: FIPRONIL SPOT ON DOG	N/A	01-Aug-2019	4 Day(s)	D-D	As reported by the animal owner, Biscuit, a 13 year old, male, Springer Spaniel dog, weighing 25 kg , reproductive status and health status unknown, and Snowy, a 13 year old, female, Springer

N/A signifies the information for this field is either not available or not applicable

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

Report printed on 25-Oct-2019 at 8:39:59PM

*indicates Approximate date or weight

Page 183 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00190

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex: X Sex qualifier: Unknown Age: 13.00 Year(s) Weight: 23 - 25 kg				Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company					Spaniel dog, weighing 23 kg, reproductive status and health status unknown, were treated with FRONTLINE SPOT ON DOG L, batch number: S21216AX, expiry date AUG 2021, administered topically between the shoulder blades, by the animal owner, on 28 JUL 2019 for an unknown indication. On 01 AUG 2019, the owner reported that they had removed 3 fleas off one of the dogs and 1 off another. The owner reported that luckily the dogs have always been flea free and that their coats are kept short. On 02 Aug 2019, the owner reported that they use the product every month, all year round. Nobody in the house is being bitten by the fleas, the dogs spend time indoors and also go to a dog walker/doggy day care. All the animals in the household have been treated with a flea product, and the dogs are not bathed or go swimming more than once a week. The dogs also do not swim or are bathed within 2 days of product administration, and the owner has lived in their house for more than a year. The owner has also treated the home with an environmental flea treatment, has washed their pets bedding at over 60 degrees Celsius, and regularly vacuums all areas of the house that the pets can access.
01-Aug-2019	UAE; 19UK002443; -, United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, approximately 2 cats (signalment otherwise unknown), were treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown, details unknown), by the animal owner, on an unknown date, for an unknown indication. The owner reported that the product doesn't work. Despite treating their cats with FRONTLINE PLUS and environment regularly, they have just removed over 60 fleas off one of the cats and 20 off another with a flea comb. The owner reported that they had followed all instructions to the letter. On 10 AUG 2019 the animal owner reported that the animals not only had live fleas (hundreds) but live larvae as well. These infested an ottoman that the animals lay on and progressed to stage three. Shaking any of their bedding displayed live fleas and larvae on a daily basis. The animal owner reports that it is obvious that the fleas have become immune to fipronil and that they have only got on top of the situation with a flea comb and the use of Advantage. The animal owner now only sees dead or dying fleas (considered resolved). Start date of event added for submission purposes only. UPDATE 16 SEP 2019: The animal owner reports that their animals did not have one or two fleas but were infested. They were literally removing hundreds of fleas off an elderly cat who rarely goes out. In addition, there were live larvae living on them. The animal owner states that they have used FRONTLINE PLUS for many years, it used to be successful but they believe that the fleas have become immune to the active ingredient fipronil. This coupled with warmer summers have resulted in extreme infestation. The animal owner reports that they have successfully tackled the problem by switching to Advantage flea treatment and Indorex house spray.
01-Aug-2019	UAE; 19UK002444; Cornwall; United Kingdom	Species: Canine Breed: Collie Sex: U Sex qualifier: Neutered Age: 11.00 Year(s) Weight: 25 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: FIPRONIL SPOT ON DOG;	14-Jul-2019	01-Aug-2019	18 Day(s)	D-D	As reported by the animal owner, Coal, an 11 year old, neutered Collie dog, sex unknown, weighing 25 kg and of good health, was treated with FRONTLINE PLUS SPOT ON DOG L (batch number: S63225AL, expiry date: OCT 2021), correctly administered topically to an unknown site, by the animal owner, on 14 JUL 2019, as a parasiticide. The owner reported that prior to FRONTLINE PLUS they had used FRONTLINE SPOT ON but was told to try FRONTLINE PLUS, however on 01 AUG 2019 they reported that they are still absolutely inundated with fleas. The owner has used a

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 184 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00191

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Route: Topical / Cutaneous Was the product used ok?: Yes					household spray and washed all the bedding. They understand the flea lifecycle and feel that it is simply not working, and so has lost all confidence in the product. On 09 AUG 2019 a staff member at a retail outlet reported that the animal owner purchased FRONTLINE PLUS SPOT ON DOG L (batch S62911AX expiry SEP 2021) for the animal. Their records state that the animal is Bill a canine weighing 23 kg and aged 3 years 2 months. It is unknown if this information is correct. Case Linked to cases 19UK002445 and 19UK002446. UPDATE 18 OCT 2019: The dog owner confirmed that the dog was called Coal. The dog owner reported that the flea product was used all the year round and had been used all of the pets lives. The last 4 dates the product was applied was 14 APR 2019, 14 MAY 2019, 14 JUN 2019 and 14 JUL 2019. The product was applied as per instructions on the packaging. The people in the home were being bitten by the fleas and they were seeing many fleas, 5 or more at the same time. The owner reported that the dogs spent most of their time indoors and outdoors (in the garden only). The dogs were never bathed and never went swimming. The owners had treated the home with an environmental flea treatment (product unknown). They had washed the pet's bedding at over 60°C and had vacuumed all areas the pets could access. The owner had lived in their home for less than 1 year.
01-Aug-2019	UAE; 19UK002445; Cornwall; United Kingdom	Species: Canine Breed: Poodle (Miniature) Sex: U Sex qualifier: Neutered Age: 5.00 Year(s) Weight: 7 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: FIPRONIL SPOT ON DOG; Environmental flea treatment; Route: Topical / Cutaneous Was the product used ok?: Yes	14-Jul-2019	01-Aug-2019	18 Day(s)	D-D	As reported by the animal owner, Honey, a 5 year old, neutered Poodle dog, sex unknown, weighing 8 kg and of good health, was treated with FRONTLINE PLUS SPOT ON DOG S (batch number: R60825AL, expiry date: MAR 2020), correctly administered topically to an unknown site, by the animal owner, on 14 JUL 2019, as a parasiticide. The owner reported that prior to FRONTLINE PLUS they had used FRONTLINE SPOT ON but was told to try FRONTLINE PLUS, however on 01 AUG 2019 they reported that they are still absolutely inundated with fleas. The owner has used a household spray and washed all the bedding. They understand the flea lifecycle and feel that it is simply not working, and so has lost all confidence in the product. On 09 AUG 2019 a staff member at a retail outlet reported that the animal owner purchased FRONTLINE PLUS SPOT ON DOG S (batch S62709BW expiry SEP 2021) for the animal. It is unknown if this information is correct. Case Linked to cases 19UK002444 and 19UK002446. UPDATE 18 OCT 2019: The dog owner confirmed that the dog was called Honey that weighed 7 kg. The dog owner reported that the flea product was used all the year round and had been used all of the pets lives. The last 4 dates the product was applied was 14 APR 2019, 14 MAY 2019, 14 JUN 2019 and 14 JUL 2019. The product was applied as per instructions on the packaging. The people in the home were being bitten by the fleas and they were seeing many fleas, 5 or more at the same time. The owner reported that the dogs spent most of their time indoors and outdoors (in the garden only). The dogs were never bathed and never went swimming. The owners had treated the home with an environmental flea treatment. They had washed the pet's bedding at over 60°C and had vacuumed all areas the pets could access. The owner had lived in their home for less than 1 year.
01-Aug-2019	UAE; 19UK002446; Meadow; United Kingdom	Species: Feline Breed: Domestic Shorthair	1	1	0	Product used: FIPRONIL 10%/S	14-Jul-2019	01-Aug-2019	18 Day(s)	D-D	As reported by the animal owner, Audry, a 7 year old, neutered Domestic Shorthair cat, sex unknown, weighing 4 kg and of good health, was treated with FRONTLINE PLUS SPOT ON CAT (batch number: R40880, expiry date: JUL 2020), correctly administered

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 185 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00192

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		(Crossbreed) Sex: U Sex qualifier: Neutered Age: 6.00 Year(s) Weight: 4 kg				METHOPRENE 12% SPOT ON Other products used: FIPRONIL SPOT ON CAT; Environmental flea treatment; Route: Topical / Cutaneous Was the product used ok?: Yes					topically to an unknown site, by the animal owner, on 14 JUL 2019, as a parasiticide. The owner reported that prior to FRONTLINE PLUS they had used FRONTLINE SPOT ON but was told to try FRONTLINE PLUS, however on 01 AUG 2019 they reported that they are still absolutely inundated with fleas. The owner has used a household spray and washed all the bedding. They understand the flea lifecycle and feel that it is simply not working, and so has lost all confidence in the product. On 09 AUG 2019 a staff member at a retail outlet reported that the animal owner purchased FRONTLINE PLUS SPOT ON CAT (batch S41113AW expiry AUG 2021) for the animal. Their records state that the animal is Bencat a feline weighing 4 kg. It is unknown if this information is correct. Case Linked to cases 19UK002444 and 19UK002445. UPDATE 18 OCT 2019: The dog owner confirmed that the dog was called Audry and was 6 years old. The dog owner reported that the flea product was used all the year round and had been used all of the pets lives. The last 4 dates the product was applied was 14 APR 2019, 14 MAY 2019, 14 JUN 2019 and 14 JUL 2019. The product was applied as per instructions on the packaging. The people in the home were being bitten by the fleas and they were seeing many fleas, 5 or more at the same time. The owner reported that the dogs spent most of their time indoors and outdoors (in the garden only). The dogs were never bathed and never went swimming. The owners had treated the home with an environmental flea treatment. They had washed the pet's bedding at over 60°C and had vacuumed all areas the pets could access. The owner had lived in their home for less than 1 year.
01-Aug-2019	UAE; 19UK002447; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	Jul-2019*	0 Day(s)	D-D	As reported by the animal owner via Social Media, a canine (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON DOG M, batch and expiry, and further details unknown) by the animal owner almost two weeks ago (estimated JUL 2019) for an unknown indication. The animal owner reported that they thought that they were all clear but unfortunately they are back and not dying. The animal owner has also sprayed the house with flea spray.
01-Aug-2019	UAE; 19UK002448; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	Jul-2019*	0 Day(s)	D-D	As reported by the animal owner via Social Media, a feline (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON CAT, batch, expiry, and further details unknown) by the animal owner almost two weeks ago (estimated JUL 2019) for an unknown indication. The animal owner reported that they thought that they were all clear but unfortunately they are back and not dying. The animal owner has also sprayed the house with flea spray.
01-Aug-2019	UAE; 19UK002449; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown	2	2	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products	N/A	Feb-2019*	N/A	D-D	As reported by the animal owner, two small to medium canines (signalment otherwise unknown) were administered FRONTLINE SPOT ON (assumed FRONTLINE SPOT ON DOG M) (batch and expiry unknown) (details unknown) by the animal owner for an unknown indication. The animal owner reports that in the last six months or so it has stopped working. They have been rigorous regarding procedures- shampoo with Beaphar, spray with Indorex

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
 Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
 *indicates Approximate date or weight

Page 186 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00193

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: - Weight: Unknown				Route: unknown Was the product used ok?: Unknown to Company					Defence Spray, and has recently used Beaphar Household Flea Powder. The animal owner is not finding many fleas on the dogs but there are enough for them to easily find. The last dose of FRONTLINE was on Monday 29 JUL 2019 and they are following instructions with respect to weight etc.
01-Aug-2019	UAE; 19UK002450; -, United Kingdom	Species: Canine Breed: Siberian Husky Sex: X Sex qualifier: Unknown Age: 6.50 Year(s) Weight: 21 - 27 kg	5	5	0	Product used: FIPRONIL SPOT ON DOG Other products used: Advantage; Route: unknown Was the product used ok?: Unknown to Company	N/A	01-Aug-2019*	12 Day(s)	D-D	As reported by the animal owner, Flash, a 6.5 year old, male, Siberian Husky dog, weighing 21 kg, Thor, a 6.5 year old, male, Siberian Husky dog, weighing 27 kg, Hulk, a 6.5 year old, male, Siberian Husky dog, weighing 23 kg, Meeka, a 11.5 year old, female, Siberian Husky dog, weighing 26 kg, and Rogue, a 6.5 year old, female, Siberian Husky dog, weighing 23 kg (signalment otherwise unknown), were treated with FRONTLINE SPOT ON DOG L (batch number: S21403AL, expiry date: SEP 2021), details unknown, by the animal owner, every month, with the last application 2 weeks ago on 20 JUL 2019, as a parasiticide. The owner reported that they purchased the product when they spotted one flea and used one treatment on 5 different dogs to try to catch them straight away. 2 weeks later the owner has had to go out and purchase more of a different brand as the FRONTLINE didn't work. The owner uses either FRONTLINE SPOT ON DOG L or Advantage every month all year round as a flea treatment for the dogs, with the last applications of a flea treatment being on 20 JUL 2019, 15 JUN 2019 (estimated as last possible use of Advantage), 11 MAY 2019, and 08 APR 2019. The owner reported that people in the house are being bitten, they are seeing between 7 and 10 fleas on their dogs, they have treated the house with a spray, and the flea treatment is not applied whilst the dogs are wearing a collar. The dogs are also bathed twice a year and don't go swimming.
02-Aug-2019	UAE; 19UK002451; Lanarkshire; United Kingdom	Species: Canine Breed: Border Collie Sex: U Sex qualifier: Unknown Age: 11.00 Year(s) Weight: 19.7 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	N/A	2019*	12 Day(s)	D-D	As reported by the head veterinary nurse, Maggie, an 11 year old Border Collie Dog, sex and reproductive status unknown, weighing 19.7 kg and of good health, was treated with FRONTLINE COMBO SPOT ON DOG M (batch number and expiry date unknown), applied topically to an unknown site, by the animal owner, last week as a preventative treatment. The vet nurse reported that they were unsure of the product compliance, although the owner had always used FRONTLINE COMBO and don't know if the owner is being bitten by fleas. One of the other nurses said that there's quite a lot of fleas in the dog's coat but was unsure how many exactly. The owner has treated the house with an unknown product. The owner would like another product and they were going to give Bravecto. Start date of event added for submission purposes only.
02-Aug-2019	UAE; 19UK002452; South Glamorgan; United Kingdom	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: M Sex qualifier: Neutered Age: 12.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: No (Treatment / vaccination program not	26-Jul-2019*	01-Aug-2019*	2 Day(s)	D-D	As reported by a member of the veterinary clinic staff, Syrus, a 12 year old, neutered male, Domestic Shorthair Cat, of unknown weight and condition, was treated with FRONTLINE SPOT ON CAT (batch number and expiry date unknown), details unknown, by the animal owner, 1 week ago (estimated as 26 JUL 2019), as a flea treatment. On 02 AUG 2019, the owner reported to the vet clinic that they had applied another pipette to the cat 4 days after the first pipette (estimated as 30 JUL 2019). The owner reported that the cat now has a bald patch at the application site and that the cat vomited. The vet advised the owner to bring the cat down to be examined/checked over but the owner refused. There is not a lot of history for this cat as it is not seen very often, however it has historically been treated with Advocate, but the reporter is sure that

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 187 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00194

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						respected)					the owner said FRONTLINE SPOT ON this time. Start date of event added for submission purposes only.
02-Aug-2019	UAE; 19UK002454; -, United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: FIPRONIL SPOT ON DOG; Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	22 Day(s)	D-D	As reported by the animal owner, approximately 2 dogs (signalment otherwise unknown), were treated with FRONTLINE PLUS (estimated as FRONTLINE PLUS SPOT ON DOG M) and FRONTLINE (estimated as FRONTLINE SPOT ON DOG M), batch number and expiry date unknown, details unknown, by the animal owner for about 20 years, with the last application 2 weeks ago (estimated as 19 JUL 2019), for an unknown indication. The owner reported that they understand how the products work, but 2 weeks after application the dogs have big and small fleas and lots of flea dirt. The owner has used flea bombs and diatomaceous powder also. Start date of event added for submission purposes only,
02-Aug-2019	UAE; 19UK002455; -, United Kingdom	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: M Sex qualifier: Neutered Age: 15.00 Year(s) Weight: 6 kg	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON; Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	N/A	14-Jul-2019	N/A	D-D	As reported by the animal owner, Scamper, a 15 year old, neutered, male Domestic Shorthair Cat, weighing 6 kg and of good health, was treated with FRONTLINE SPOT ON CAT, administered topically to the back of the neck, by the animal owner, on 14 JUL 2019 for an unknown indication. The owner reported that they have been using FRONTLINE SPOT ON and FRONTLINE PLUS SPOT ON CAT for a long time, alternating each month. The owner forgot to give it and left about a 2 week gap between treatments. After the most recent application the owner noticed the cat scratching but thought nothing of it. The owner then combed the cat and noticed lots of fleas in his coat, seeing 30 fleas once. They have looked online about fleas and how to get rid of them and are aware of the pupae stage and that nothing can kill it. The owner was going to bleach the floors and windows but read that the cat may get it on its paws and lick them. They also read that putting salt on the carpet will cause the fleas to become dehydrated. The owner has stopped the cat from going into certain rooms and the owner reported that they are not being bitten but are aware that there is probably a home infestation in the house.
04-Aug-2019	UAE; 19UK002456; -, United Kingdom	Species: Feline Breed: Feline (unknown) Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: No (Treatment / vaccination program not respected)	30-Jun-2019*	21-Jul-2019	0 Day(s)	D-D	As reported by the animal owner, Bear, a male cat, of unknown weight and condition (signalment otherwise unknown), was treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), details unknown, by the animal owner, on 21 JUL 2019, for an unknown indication. The owner reported that they have treated their cat with FRONTLINE PLUS twice in the last 5 weeks, and put the second application on after only 3 weeks, as the first application didn't seem to be working. The cat still has visible fleas following the last application on 21 JUL 2019. The owner reported that the product is in date and wondered whether his weight would affect the treatment as he is so big (weight not provided) and do they need to increase the dosage. The fleas are making the cat so miserable. The cat is a hunter and regularly brings home dead mice or birds which the owner believes is where he gets the fleas from. On 23 AUG 2019 the owner reported that they have applied the last vial to Bear. They report that this one was definitely full as it bubbled when they snapped it and some leaked onto their skin (reported in linked case 19UK002777) when they applied it. The other two vials didn't and Bear was still scratching and they observed live fleas crawling over him long after

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 188 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00195

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											it was supposed to take effect. The owner thinks they must have had a bad batch with the other 2 vials being empty. The have just applied the last vial to Bear. UPDATE 03 SEP 2019: The animal owner reports that the animal seems a lot better after this application of FRONTLINE (outcome changed to recovered). They seriously believe that the first two vials were empty as the product has always worked in the past. UPDATE 24 SEP 2019: QA results received. Investigation completed for FIPRONIL 10%/S METHOPRENE 12% SPOT ON Lot unknown, expiry . Case investigated by France - Toulouse. Final complaint evaluation An adverse event for FRONTLINE PLUS SPOT ON CATS, batch unknown, was received by BIAH QA on the 28th of
03-Aug-2019	UAE; 19UK002458; -; United Kingdom	Species: Canine Breed: Retriever (Labrador, Black) Sex: F Sex qualifier: Unknown Age: - Weight: 30 - 35 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: No (Treatment / vaccination program not respected)	10-Jul-2019	24-Jul-2019	N/A	D-D	As reported by the animal owner, a female, Black Labrador Retriever dog, weighing between 30 and 35 kg (signalment otherwise unknown), was treated with FRONTLINE SPOT ON DOG L (batch number and expiry date unknown), details unknown, by the animal owner, on 10 JUL 2019 and again on 24 JUL 2019, for an unknown indication. The owner reported that after the first application on 10 JUL 2019 she was worried the dog was still scratching and so gave her a second pipette. On 3 AUG 2019 the owner reported that whilst brushing the dog they noticed that she is crawling with fleas. The owner applied the product carefully and according to the instructions. The dog has had a sore on her neck due to scratching which the owner sorted out with a collar and treatment but now she has one on one of her teats from scratching which is really hard to stop her from doing. The owner has now used FRONTLINE SPRAY on the dog that they had for their kitten, and they are now going to de-flea the kitten again.
05-Aug-2019	UAE; 19UK002460; -; United Kingdom	Species: Canine Breed: Retriever (Golden) Sex: X Sex qualifier: Unknown Age: 2.00 Year(s) Weight: 30 - 32 kg	3	3	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	27-Jul-2019	05-Aug-2019	9 Day(s)	D-D	As reported by the animal owner, Honey, a 12 year old, female, Golden Retriever dog, weighing 32 kg, reproductive status and health status unknown, and Tim and Ben, two 2 year old Golden Retriever dogs, both weighing 30 kg, reproductive status and health status unknown, were treated with FRONTLINE SPOT ON DOG L (batch number: S21216AX, expiry date: AUG 2021), applied topically between the shoulder blades, by the animal owner, on 27 JUL 2019, for an unknown indication. The owner reported on 05 Aug 2019 that all of the dogs were scratching themselves continuously and that they were horrified to find they are all alive after 24 hours with very active fleas. The owner reported that obviously the treatment has not worked and is wondering if they have received a faulty batch as the dogs were scratching themselves to bits. Fortunately, where the dogs are allowed there are no soft furnishings, and the dogs have plastic beds with soft covers which were all washed at a hot temperature the same time as treatment. The owner then reported that they treat each of their pets about once a year, and that for their current flea issue, which they noticed on 05 AUG 2019. They did not have a flea issue when they applied the FRONTLINE. People in the home are not being bitten by fleas, the dogs spend time both indoors and outdoors, however due to the heat for the last month they have not been outside very often, and all animals in the household and all in contact animals have been treated with a flea product. The owner is seeing many fleas-5 or more at the same time on the dogs, the dogs are never bathed and never go swimming, and the owner has lived in their house for more than a year, which is a rural property. The dogs are covered in jumping

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 189 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00196

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											fleas and flea muck which they did not have before. The dog's bedding is washed every week and beds are scrubbed out weekly. They also vacuum at least twice a day. The owner stated that they do not use FRONTLINE as recommended because they are not
05-Aug-2019	UAE; 19UK002461; -; United Kingdom	Species: Canine Breed: Spaniel (Cocker) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	Feb-2019*	N/A	D-D	As reported by the animal owner, a Cocker Spaniel dog (signalment otherwise unknown), was treated with FRONTLINE (estimated as FRONTLINE SPOT ON DOG M), batch number and expiry date unknown, details unknown, by the animal owner, on an unknown date, for an unknown indication. The owner reported that they have found the product isn't working and for the past 6 months they have had to buy over the counter products to help the dog with fleas. Start date of event added for submission purposes only. UPDATE 23 AUG 2019: The product was confirmed as FRONTLINE PLUS SPOT ON DOG M (batch T60224A expiry DEC 2021).
01-Aug-2019	UAE; 19UK002464; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, 2 cats (signalment otherwise unknown), were treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), details unknown, by the animal owner, every month, for an unknown indication. The owner reported that at the moment the are combing the 2 cats every day and finding that FRONTLINE is not effective. Start date of event added for submission purposes only.
27-Jul-2019	UAE; 19UK002467; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner via social media, a male canine (signalment otherwise unknown) was given FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG M, batch and expiry unknown) by the animal owner (details otherwise unknown). The animal owner reports that their house has been treated but the dog seems to get re-infested quickly. The animal owner lives in the country and walks the dog in fields. Start date for submission purposes only.
05-Aug-2019	UAE; 19UK002472; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: FIPRONIL SPOT ON DOG; Route: unknown Was the product used ok?: Unknown	N/A	2019*	N/A	D-D	As reported by the animal owner, approximately 2 dogs (signalment otherwise unknown), were treated with FRONTLINE PLUS (estimated as FRONTLINE PLUS SPOT ON DOG M), batch number and expiry date unknown, details unknown, by the animal owner, for 3 months, for an unknown indication. The owner reported that they have been a FRONTLINE (estimated as FRONTLINE SPOT ON DOG M) user for many years when they progressed to FRONTLINE PLUS as the fleas had become immune to it, they naturally went with the upgraded version for the best. The owner had never seen a flea before and so they didn't know what the problem was as they were not being bitten at the time. The owner carried on as before, then after using FRONTLINE PLUS for 3 months they had a nightmare happen.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 190 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00197

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						to Company					The owner threw out the carpets, curtains and cushions, and engulfed the house with flea spray from the vets. The owner spoke to their vet and showed them the beasts and were mortified and embarrassed because in over 40 years of owning cats and dogs this had never happened. Within a couple of days with the vet treatments the owner reported that they are hopefully now clear. Start date of event added for submission purposes only. Case linked to case 19UK002473.
05-Aug-2019	UAE; 19UK002473; -, United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: FIPRONIL SPOT ON CAT; Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, approximately 2 cats (signalment otherwise unknown), were treated with FRONTLINE PLUS SPOT ON CAT, batch number and expiry date unknown, details unknown, by the animal owner, for 3 months, for an unknown indication. The owner reported that they have been a FRONTLINE SPOT ON CAT user for many years when they progressed to FRONTLINE PLUS as the fleas had become immune to it, they naturally went with the upgraded version for the best. The owner had never seen a flea before and so they didn't know what the problem was as they were not being bitten at the time. The owner carried on as before, then after using FRONTLINE PLUS for 3 months they had a nightmare happen. The owner threw out the carpets, curtains and cushions, and engulfed the house with flea spray from the vets. The owner spoke to their vet and showed them the beasts and were mortified and embarrassed because in over 40 years of owning cats and dogs this had never happened. Within a couple of days with the vet treatments the owner reported that they are hopefully now clear. Start date of event added for submission purposes only. Case lined to case 19UK002472.
05-Aug-2019	UAE; 19UK002475; -, United Kingdom	Species: Feline Breed: Feline (unknown) Sex: F Sex qualifier: Unknown Age: 11.00 Year(s) Weight: 5.45 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: FIPRONIL SPOT ON CAT; Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	19-May-2019*	May-2019*	N/A	D-D	As reported by the animal owner, Ziggy, an 11 year old, female Moggy cat, weighing 5.45 kg, health status unknown, reproductive status unknown, was treated with FRONTLINE SPOT ON CAT (batch number and expiry date unknown), with 2 dabs applied topically to the back of the neck after parting the fur, by the animal owner, every month since OCT 2018, for an unknown indication. On 05 AUG 2019 the owner reported that when they combed the cat there were 9 fleas on her and they also found a live one jumping around in their toddler's bedroom. The owner even switched to FRONTLINE PLUS 2 months ago. On 07 AUG 2019 the owner reported that they used FRONTLINE SPOT ON until MAY 2019, with the last application on 21 APR 2019, when they switched to FRONTLINE PLUS SPOT ON CAT (batch number: S41113AW, expiry date: AUG 2021). They applied the FRONTLINE PLUS on 19 MAY 2019, 15 JUN 2019, and 14 JUL 2019, after noticing their current flea issue in MAY 2019. The owner also reported that people in the home are being bitten by fleas, with their son having 2 red bumps on his arm that could be bites on 07 AUG 2019. The owner is seeing many fleas on their cat at one time, with more than 5 at a time seen, and 10 were found on the cat on 06 AUG 2019. The cat goes indoors and outdoors, all animals in the household and all in contact animals have been treated with a flea product, the cat never gets bathed or goes swimming, and the owner has lived in their house for more than a year. The owner has treated the house with an environmental flea treatment, has washed all of their pet's bedding at over 60 degrees Celsius and regularly vacuums all areas that the cat can access. The owner also reported that their sofa is covered in flea eggs every morning after the cat has been sleeping on it, which are definitely white as the sofa is dark brown so they show up like salt

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 191 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00198

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											has been sprinkled on it.
05-Aug-2019	UAE; 19UK002476; -, United Kingdom	Species: Canine Breed: Canine Other Sex: M Sex qualifier: Unknown Age: 6.00 Year(s) Weight: 17.5 kg	1	1	0	Product used: FIPRONIL SPRAY Other products used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON; Strikeback Kill Spray; Wipeout Flea Spray; Route: unknown Was the product used ok?: Unknown to Company	30-May-2019*	14-Jul-2019*	0 Day(s)	D-D	As reported by the animal owner, Bandit, a 6 year old, male, mixed breed dog, weighing 17.5 kg, health status unknown, reproductive status unknown, was treated with FRONTLINE SPRAY (batch number: 083274113, expiry date unknown), details unknown, by the animal owner, a few months ago (approximately 30 MAY 2019, 30 JUN 2019, and 14 JUL 2019), for an unknown indication. The owner reported that have never before had flea problems, however a month after using the FRONTLINE SPRAY, their dog and 2 cats all have fleas. The owner went to a large pet retailer and explained the problem and was advised that the spray wasn't very good and to use a spot on treatment. The owner was reluctant to use FRONTLINE again since it didn't appear to have worked, but since the error may have been theirs for using the spray, they were persuaded by the staff member to upgrade to FRONTLINE PLUS SPOT ON DOG M on 21 JUL 2019. Aside from using the FRONTLINE PLUS, the owner has also washed every washable fabric in their home including the pets bedding at over 60 degrees Celsius, they have hoovered twice daily plus used a house spray (Strikeback kill spray and Wipeout flea spray) on every surface and inch of their house. 2 weeks on, their animals are still riddled with fleas. The staff member who prescribed the dose had accurate weights and the owner followed the instructions correctly. The owner reported that the product does not appear to be effective. They were advised by the staff member that they must keep using the product for it to be effective but they are concerned that they are saying this to keep them spending money rather than tackle the problem. Two weeks in, the owners pets are raw from scratching. The owner also reported that they use the product all year round, people in the house are being bitten, and that the dog spends time indoors but also goes out on walks but never off the lead. The owner's cats also spend time indoors, but also go outside between 2-3 times a week, usually at
05-Aug-2019	UAE; 19UK002477; -, United Kingdom	Species: Feline Breed: Feline Other Sex: X Sex qualifier: Unknown Age: 2.00 Year(s) Weight: 3.8 - 4 kg	2	2	0	Product used: FIPRONIL SPRAY Other products used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON; Strikeback Kill Spray; Wipeout Flea Spray; Route: unknown Was the product used ok?: Unknown to Company	30-May-2019*	14-Jul-2019*	0 Day(s)	D-D	As reported by the animal owner, Pilgrim, a 2 year old, male, mixed breed cat, weighing 4 kg, health status unknown, reproductive status unknown, and Sabre, a 2 year old, female, mixed breed cat, weighing 3.8 kg, health status unknown, reproductive status unknown, were treated with FRONTLINE SPRAY (batch number and expiry date unknown), details unknown, by the animal owner, for an unknown indication. Dates of treatment were 30 MAY 2019, 30 JUN 2019 and 14 JUL 2019 (when they first saw a flea). The owner reported that have never before had flea problems, however their dog and 2 cats all have fleas (first flea seen on 14 JUL 2019). The owner went to a large pet retailer and explained the problem and was advised that the spray wasn't very good and to use a spot on treatment. The owner was reluctant to use FRONTLINE again since it didn't appear to have worked, but since the error may have been theirs for using the spray, they were persuaded by the staff member to upgrade to FRONTLINE PLUS SPOT ON CAT on 21 JUL 2019. Aside from using the FRONTLINE PLUS, the owner has also washed every washable fabric in their home including the pets bedding at over 60 degrees Celsius, they have hoovered twice daily plus used a house spray on every surface and inch of their house (Strikeback kill spray and Wipeout flea spray and room bombs). 2 weeks on, their animals are still riddled with fleas. The staff member who prescribed the dose had accurate weights and the owner followed the instructions correctly. The owner reported

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 192 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00199

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											that the product does not appear to be effective . They were advised by the staff member that they must keep using the product for it to be effective but they are concerned that they are saying this to keep them spending money rather than tackle the problem. Two weeks in, the owners pets are raw from scratching. The owner also reported that they use the product all year round, people in the house are being bitten, and that the dog spends time indoors but also goes
06-Aug-2019	UAE; 19UK002479; -; United Kingdom	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: M Sex qualifier: Unknown Age: 16.00 Year(s) Weight: 4.1 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	N/A	26-Jul-2019	1 Week(s)	D-D	As reported by the animal owner, Benjamin, a 16 year old, male, Domestic Shorthair cat, weighing 4.1 kg, reproductive status unknown, health status unknown, was treated with FRONTLINE PLUS SPOT ON CAT (batch number: S41303AW, expiry date: OCT 2021), applied topically to the back of the neck, by the animal owner, on 19 JUL 2019, for an unknown indication. The owner reported that they were on holiday for a week but on returning home their cat is still flea infested. The owner has not had any difficulty in the past and the treatment was in date . The product is used all year round, but only when the owner sees fleas on the cat, with previous application in the last week of JUN 2019 (estimated as 23 JUN 2019). People in the house are not being bitten by the fleas, all the animals in the household and all in contact animals have been treated with a flea product, and the owner is seeing many fleas, 10-20 at the same time on the cat. The cat never gets bathed and never goes swimming, the owner has lived in their house for more than a year, and they have regularly vacuumed all areas the pet can access and washed their pets bedding at over 60 degrees Celsius, however they have not treated their home with an environmental flea treatment.
06-Aug-2019	UAE; 19UK002483; -; United Kingdom	Species: Canine Breed: Airedale Terrier Sex: M Sex qualifier: Neutered Age: 1.00 Year(s) Weight: 30 kg	2	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	May-2019*	Jun-2019*	0 Day(s)	D-D	As reported by the animal owner, Loki, a 1 year old, neutered, male, Airedale Terrier dog, weighing 30 kg and of good health, was treated with FRONTLINE PLUS SPOT ON DOG L (batch number and expiry date unknown), correctly applied topically to the back of the neck, by the animal owner, in MAY 2019, for an unknown indication. The owner reported that their 2 dogs were given FRONTLINE PLUS, and one of the dogs has developed an itchy skin condition. This did not develop immediately after having the FRONTLINE. A week after having it, the dogs went into kennels and after 2 weeks in kennels the dog was collected and that's when the owner noticed the dog was very itchy. The owner thought this may be flea related (though no fleas have ever been seen on either of the dogs). 6 weeks after the first administration, the owner gave another FRONTLINE. The itchiness did not stop so they took the dog to the vets, and they gave him Piriton, and a 48 hour antihistamine (unsure which product). These didn't work. The dog is now on hypoallergenic food. The itching is finally easing now after 4 weeks. The skin has not appeared problematic at all, with no rash/redness/scabs etc. observed, the skin was normal all over.
06-Aug-2019	UAE; 19UK002485; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown	23-Jul-2019*	23-Jul-2019*	0 Day(s)	D-D	As reported by the animal owner, 2 dogs (signalment otherwise unknown), were treated with FRONTLINE PLUS (estimated as FRONTLINE PLUS SPOT ON DOG M), batch number and expiry date unknown, details unknown, by the animal owner, 2 weeks ago, as a parasiticide. The owner reported that when they purchased the product, both dogs had fleas and ticks. They had never used this product before. The owner dutifully read the instructions and used the product, and 10 days later the ticks had gone but the dogs were still infested with fleas. The owner had to

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
 Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
 *indicates Approximate date or weight

Page 193 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00200

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Was the product used ok?: Unknown to Company					go to the vet and buy some more tablets and the fleas have now gone.
06-Aug-2019	UAE; 19UK002487; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: M Sex qualifier: Unknown Age: 3.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: No (Indication not indicated / recommended)	N/A	2019*	N/A	D-D	As reported by the animal owner, a 3 year old, male cat (signalment otherwise unknown), was treated with FRONTLINE SPOT ON CAT (batch number and expiry date unknown), details unknown, by the animal owner, regularly, for an unknown indication. The owner reported that the cat has recently been taken to the vets and has been diagnosed with an intolerance to harvest mite bites. The cat got a steroid injection plus an antibiotic injection to try and help. The cat is regularly treated with FRONTLINE SPOT ON CAT but the owner has ordered FRONTLINE PLUS SPOT ON CAT as they have read quite a few times this will kill the mites within 48 hours. Start date of event added for submission purposes only.
07-Aug-2019	UAE; 19UK002492; -; United Kingdom	Species: Canine Breed: Retriever (Flat-Coat) Sex: M Sex qualifier: - Age: 24.70 Year(s) Weight: 32 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	N/A	21-Jul-2019	within 2 minutes	D-B	Collapsed on his side and frothed at the mouth less than 2 minutes, reaction duration 24 hours UPDATE 29 AUG 2019: QA results received. Investigation completed for FIPRONIL SPOT ON DOG Lot S21516AX, expiry 2021-09-30. Case investigated by France - Toulouse. Final complaint evaluation product quality complaint for FRONTLINE SPOT ON DOG M, batch number S21516AX, was received by BIAH QA on the 12th of August 2019. The complaint description is: Adverse Event. This is the first complaint for this batch. The complaint sample is not received and pictures are not attached to this case. The retention sample is not reviewed because it is stored for identification purposes. Therefore, it is not applicable to this kind of defect. Batch records investigation: Batch record review: S215. Manufacturing date: 29/10/2018 - Expiry date: NA - Manufacturing quantity: 1199.4 liters. Associated deviation(s): No deviation associated to this batch. Change control associated: This batch was not concerned by any change control. Observation(s): No observation associated to this batch Results of QC testing: Conform at specifications. All parameters verified during manufacturing of this bulk batch are conform. Batch record review: S21516. Manufacturing date: 14/11/2018 - Expiry date: 09/2021 - Manufacturing quantity: 16670 blisters. Associated deviation(s): No deviation associated to this batch. Change control associated: This batch was not concerned by any change control. Observation(s): No observation associated to this batch. In-process controls on vials, including aspect and filling of vials, were performed every 30 minutes. 132 vials were checked during IPC and were conform. Root cause : No root cause could be identified on Toulouse plant. After verification of batch records and certificate of analysis, no relation can be established between this related adverse event and the manufacturing process on Toulouse plant. Conclusion: This defect is not linked to any product quality issue.
07-Aug-2019	UAE; 19UK002504; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products	N/A	05-Aug-2019	0 Day(s)	D-D	As reported by the animal owner, approximately 2 cats (signalment otherwise unknown), were treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), details unknown, by the animal owner, 48 hours ago (05 AUG 2019), for an unknown indication. The owner reported that their cats still have fleas 48 hours after application.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 194 of 867

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00201

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: - Weight: Unknown				used: no other products Route: unknown Was the product used ok?: Unknown to Company					
07-Aug-2019	UAE; 19UK002505; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	07-Aug-2019	1 Week(s)	D-D	As reported by the animal owner, a male cat (signalment otherwise unknown), was treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), details unknown, by the animal owner, 1 week ago (estimated as 31 JUL 2019), for an unknown indication. The owner reported that they found a live flea on their cat 1 week after applying the FRONTLINE PLUS. The cat is an outdoor cat.
08-Aug-2019	UAE; 19UK002508; -; United Kingdom	Species: Canine Breed: Spaniel (Cocker) Sex: F Sex qualifier: Unknown Age: 4.50 Year(s) Weight: 12 - 15 kg	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	N/A	27-Jul-2019	N/A	D-D	As reported by the animal owner, Penny, a 9 year old, female, Cocker Spaniel dog, weighing 15 kg, health status unknown, reproductive status unknown, and Katie, a 4 year 6 month old, female, Cocker Spaniel dog, weighing 12 kg, health status unknown, reproductive status unknown, were treated with FRONTLINE PLUS SPOT ON DOG M (batch number and expiry date unknown) applied topically between the shoulders, by the animal owner, 11 days ago (28 JUL 2019), for an unknown indication. The owner reported that they are still getting quite a few fleas on both dogs, and that they did follow application instructions correctly. The owner first noticed their current flea problem on 27 JUL 2019 and normally flea treats their pets only when they see fleas on them. The owner also reported that people in the house are being bitten by the fleas, the dogs spend time both indoors and outdoors, all animals in the household and all in contact animals have been treated with a flea product, they are finding occasional fleas on their pets, less than 5 at a time, that their pets are not bathed or go swimming more than once a week with this occurring more than 2 days after product administration. The owner has lived in their house for more than a year and they have treated their house with an environmental flea treatment, washed their pets bedding at over 60 degrees Celsius, and regularly vacuum all areas the pets can access.
08-Aug-2019	UAE; 19UK002510; -; United Kingdom	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: F Sex qualifier: Unknown Age: 3.00 Year(s) Weight: 3.5 kg	2	2	0	Product used: FIPRONIL SPOT ON CAT Other products used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON; Indorex; Route: Topical / Cutaneous Was the	N/A	2019*	N/A	D-D	As reported by the animal owner, Sparkle and Twinkle, two 3 year old female Domestic Short Hair felines, weighing 3.5 kg, were treated with FRONTLINE SPOT ON CAT (batch number S20308AW and expiry date FEB 2021), topically to the shoulder blades, by the animal owner, monthly all year round on an unknown date, for an unknown indication. The owner reported that both cats have fleas and they used FRONTLINE SPOT ON in the first instance. They were aware that the cats still had fleas so upgraded to FRONTLINE PLUS SPOT ON CAT (batch number S41113AW and expiry date AUG 2021). The owner then became aware that the next solution had not worked either and they have now ordered Indorex defence spray (batch 91061A019 expiry APR 2021) to kill fleas in the home. The owner still has a flea problem

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 195 of 867

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00202

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						product used ok?: Unknown to Company					and the cats are obviously uncomfortable with the amount of scratching and cleaning they are giving themselves. The owner also has multiple flea bites on themselves, and their children have also been affected with unsightly flea bites across their ankles, legs and arms. The animal owner adds that they have used the product monthly to prevent fleas since they acquired the animals. They first noticed fleas on their pets on 26 JUL 2019 when they reapplied the second dose within the month. The last four dates that the animal owner applied the product were 26 JUL 2019, 11 JUL 2019, 11 JUN 2019 and 11 MAY 2019. The animals spend time indoors and outdoors, all animals that live in the household or are in-contact have been treated with a flea product and the animal owner is seeing many fleas - 5 or more at the same time. The animals are never bathed nor go swimming and the animal owner has treated the home with an environmental flea treatment, washed the pets' bedding at over 60 degrees and regularly vacuumed all areas that the pets can access. The animal owner adds that since making the enquiry they have needed to make a doctors appointment for their daughter who was given a course of antibiotics
08-Aug-2019	UAE; 19UK002517; -, United Kingdom	Species: Canine Breed: Terrier (Jack Russell) Sex: M Sex qualifier: Unknown Age: 7.00 Year(s) Weight: 6 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: Bob Martin; Route: Topical / Cutaneous Was the product used ok?: Yes	31-Jul-2019	Jul-2019*	0 Day(s)	D-D	As reported by the animal owner, a 7 year old, male, Jack Russell dog, weighing 6 kg, of good health, reproductive status unknown, was treated with FRONTLINE SPOT ON DOG S (batch number and expiry date unknown), administered topically to an unknown site, by the animal owner, on 31 JUL 2019, for an unknown indication. The owner reported that the dog wasn't due for a treatment as he had already had Bob Martin on board, but the owner saw fleas so applied FRONTLINE. The dog has always been treated with other products well within the time frame and no gaps have been left. Only 4 fleas have been seen on the dog, however the owner is being bitten but only when they are sat with the dog, and the owner's husband has had a few bites too. The owner has been regularly Hoovering, washing bedding on 60 degrees for the last week. The dog's skin is very red and he is gnawing and scratching. He has red 'boy bits' and undercarriage. Start date of event added for submission purposes only.
09-Aug-2019	UAE; 19UK002532; -, United Kingdom	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: M Sex qualifier: Neutered Age: 9.00 Year(s) Weight: 4.5 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: FRONTLINE PETCARE HOME AND ENVIRONMENT FLEA SPRAY; Route: Topical / Cutaneous Was the product used ok?: Yes	N/A	26-Jul-2019	N/A	D-D	As reported by the animal owner, Blake, a 9 year old, neutered, male, Domestic Shorthair cat, weighing 4.5 kg and of good health, was treated with FRONTLINE PLUS SPOT ON CAT (batch number: S41303AW, expiry date: OCT 2021), applied topically to an unknown site, by the animal owner on 27 JUL 2019, as a parasiticide. The owner reported that despite using FRONTLINE PLUS and FRONTLINE PETCARE HOMEGARD HOUSEHOLD FLEA SPRAY (batch number: 9162500A, expiry date: APR 2021), they are still seeing many fleas. All of the family are being bitten and the owner is physically seeing fleas jumping about on the carpet.
09-Aug-2019	UAE; 19UK002535; -, United Kingdom	Species: Feline Breed: Feline (unknown)	2	2	0	Product used: FIPRONIL 10%/S	14-Jul-2019	28-Jul-2019*	2 Week(s)	D-D	As reported by the animal owner, 2 cats (signalment otherwise unknown), were treated with FRONTLINE PLUS SPOT ON CAT (batch number: S41113AW, expiry date: AUG 2021), details

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 196 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00203

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex: U Sex qualifier: Unknown Age: - Weight: Unknown				METHOPRENE 12% SPOT ON Other products used: Advocate; Route: unknown Was the product used ok?: Unknown to Company					unknown, by the animal owner, on 14 JUL 2019, for an unknown indication. The owner reported that the product doesn't work. They have had cats for 30 years, and they have used things like this for as long as its been out, and usually they use a different brand (Advocate), but they couldn't go to the vets so they got FRONTLINE PLUS from a shop instead. The owner's 2 cats are outdoor cats that are not bathed. The owner started using FRONTLINE on 14 JUL 2019 because they were scratching like mad and could see fleas on them. 2 weeks later the fleas are still there, with the owner seeing 3 ish fleas. The cats are treated once a month for 10 months of the year.
09-Aug-2019	UAE; 19UK002537; -, United Kingdom	Species: Canine Breed: Canine (unknown) Sex: F Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	08-Aug-2019	0 Day(s)	D-D	As reported by the animal owner, a female dog (signalment otherwise unknown), was treated with FRONTLINE SPOT ON (estimated as FRONTLINE SPOT ON DOG M), batch number and expiry date unknown, details unknown, by the animal owner, on 08 AUG 2019, for an unknown indication. The owner reported that after the applied the FRONTLINE SPOT ON the dog was shaking at first for at least 30 minutes and very sheepish (coded as subdued) for the rest of the evening. The dog stayed in her bed. The dog seems ok today though (09 AUG 2019).
09-Aug-2019	UAE; 19UK002538; L37 7EH; United Kingdom	Species: Feline Breed: Feline various breeds Sex: M Sex qualifier: Unknown Age: 5.00 Year(s) Weight: 6 - 8.6 kg	2	2	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	May-2019*	May-2019*	N/A	D-D	As reported by the animal owner, two felines, Monty a male British Shorthair aged 5 years and weighing 8.6 kg, and Dave a male weighing 6 kg (signalment otherwise unknown), were treated with FRONTLINE SPOT ON CAT (batch number: S21204AW, expiry date: AUG 2021), to the back of the neck, by the animal owner, on an unknown date, for an unknown indication. The owner reported that they noticed this particular lot of flea treatment did not seem to treat the fleas on their 2 cats. The owner usually finds that it works and they are obviously much more comfortable, but not this time. The animal owner does not know the exact dates of product application but has used the product monthly on both cats for the last few months. The animal owner is constantly finding fleas and people in the home are being bitten. The cats spend time indoors and outdoors, all animals in the home have been treated, the animal owner is seeing multiple fleas at a time, the pets do not get bathed or go swimming, the animal owners have not lived in the home for less than a year and all areas the pets access are regularly vacuumed. Start date of event added for submission purposes only.
09-Aug-2019	UAE; 19UK002545; -, United Kingdom	Species: Feline Breed: Feline (unknown) Sex: F Sex qualifier: Unknown Age: 12.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: FRONTLINE PETCARE HOME AND ENVIRONMENT FLEA SPRAY; Route: unknown Was the product used ok?: Unknown	N/A	06-Aug-2019*	N/A	D-D	As reported by the animal owner, an approximately 12 year old female feline (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON CAT, batch, expiry and further details unknown) about a week ago (estimated AUG 2019) for fleas. The animal owner also used FRONTLINE PETCARE HOMEGARD HOUSEHOLD FLEA SPRAY (batch and expiry unknown) was used on 06 AUG 2019 to help with a minor infestation. The animal owner reported that they followed the instructions on the can to the letter and yet three days later, if anything it seems to have made the problem worse. It has not worked at all. The animal owner used the whole can to spread over their one bedroom flat. The animal owner adds that they first noticed the fleas about 3 weeks ago and have lived in their home for almost 6 years. The animal owner has not used FRONTLINE PETCARE HOMEGARD in the last six months but had a similar

N/A signifies the information for this field is either not available or not applicable

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

Report printed on 25-Oct-2019 at 8:39:59PM

*indicates Approximate date or weight

Page 197 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00204

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						to Company					issue about 4 years ago and used Indorex with 100 percent success. The animal owner reports that every single room in the flat was treated and every nook and cranny, and that they took all cleaning precautions - treated the cat, washed everything a flea could cling to including their daughter's teddy collection. The animal has barely come into the house since this problem arose and the animal owner doesn't see any fleas on the animal apart from the odd one or two that run across the white bit on her chin. The animal owner woke up the other morning and as soon as they put their foot on the floor they were jumped on by at least six of the little beasts. The animal has also got a brand new flea collar and says that the cat isn't really an issue, she always has a flea collar on and they treat her at the first sign of issues. The animal owner reported that they are still being attacked and that it says 12 month protection on the can and they have barely seen a day's worth of freedom since using it. The animal owner adds that they purchased the HOMEGARD with the promise that if they
09-Aug-2019	UAE; 19UK002546; Yorkshire; United Kingdom	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: M Sex qualifier: Neutered Age: 2.00 Year(s) Weight: 6.18 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	N/A	06-Aug-2019	N/A	D-C	As reported by a veterinary nurse, Rusty, a 2 year old, Neutered, Male, Domestic Shorthair cat, weighing 6.18 kg, and of good health, was treated with FRONTLINE PLUS SPOT ON CAT (batch number: S41303AW, expiry date: OCT 2021), administered topically to an unknown site, by the animal owner, on 06 AUG 2019, for an unknown indication. The vet nurse reported that the cat had previously reacted to Profender a couple of years ago, with it causing a local skin reaction that was red and sore. Not long after the FRONTLINE PLUS application on 06 AUG 2019, the skin at the application site went red and raw, itchy. There was no hair loss. The cat came into the practice that day and had a steroid injection of Depo-Medrone. The vet assumed the issue had resolved as there has been no further contact from the pet owner.
12-Aug-2019	UAE; 19UK002550; -, United Kingdom	Species: Feline Breed: Feline (unknown) Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	22-Jul-2019*	0 Day(s)	D-D	As reported by the animal owner, a white, male cat (signalment otherwise unknown), was treated with FRONTLINE PLUS SPOT ON CAT (batch number: SW40711AW, expiry date: MAY 2021), details unknown, by the animal owner, 3 or 4 weeks ago (estimated as 22 JUL 2019), for an unknown indication. The owner reported that they moved into their partner's flat, who had lived there for 6 months already, and the cat came out of nowhere and moved in. The cat started showing up, came into the house all the time before FRONTLINE PLUS was applied. The owner treated him about 3-4 weeks ago as he wouldn't stop scratching. The owner doesn't think there have been any pets in the flat previously, but is not sure. People might have been bitten. The flat has not been treated and the owner is seeing 1 to 2 fleas at a time. Start date of event added for submission purposes only.
11-Aug-2019	UAE; 19UK002551; -, United Kingdom	Species: Feline Breed: Feline (unknown) Sex: F Sex qualifier: Unknown Age: 12.00 Week(s) Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown	04-Aug-2019*	04-Aug-2019	0 Day(s)	D-D	As reported by the animal owner, a 12 week old, female kitten (signalment otherwise unknown), was treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), details unknown, by the animal owner, a week ago (estimated as 04 AUG 2019), for an unknown indication. The owner reported that the kitten is still covered in fleas.

N/A signifies the information for this field is either not available or not applicable

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

Report printed on 25-Oct-2019 at 8:39:59PM

*indicates Approximate date or weight

Page 198 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00205

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
10-Aug-2019	UAE; 19UK002553; -, United Kingdom	Species: Feline Breed: Feline (unknown) Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	to Company Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	2016*	2019*	0 Day(s)	D-D	As reported by the animal owner, a male feline (signalment otherwise unknown) was administered FRONTLINE SPOT ON CAT (batch S20703AW expiry APR 2021, details unknown) at a dose of once monthly by the animal owner for an unknown indication. The animal owner reports that they have used this product for many years, but the recent batch of six pipettes have been totally ineffective. The product is applied correctly at monthly intervals but at daily grooming, using a flea comb and brush, they animal owner finds at least two adult fleas and a few juveniles. A couple of months ago the animal was in a cattery for a week and was treated with FRONTLINE a week prior to this. The animal owner was shocked to be told when they collected the animal that they had found fleas and had applied a further one off treatment with another product. The animal owner has now used all the pipettes and will not be buying the product again. The animal owner states that either this was a faulty batch or fleas are now resistant to the medication. The animal owner added that they are well aware of the flea lifecycle, the need to keep pet bedding clean and the regular use of the product correctly applied. They have used FRONTLINE SPOT ON for several years and only this year have had problems. The animal owner states that they do know of others who have found the same problem (no further information available). UPDATE 06 SEP 2019: QA results received. Investigation completed for FIPRONIL SPOT ON CAT Lot S20703AW, expiry 2021-04-30. Final complaint evaluation product quality complaint for FRONTLINE SPOT ON CAT, batch number S20703AW, was received by BIAH QA on the 20th of August 2019. The complaint description is: Lack of efficacy. This is the first complaint for this batch. The complaint sample is not received and pictures are not attached to this case. The retention sample is not reviewed because it is stored for identification purposes. Therefore, it is not applicable to this kind of defect.
12-Aug-2019	UAE; 19UK002556; -, United Kingdom	Species: Feline Breed: Feline (unknown) Sex: X Sex qualifier: Unknown Age: 12.00 Week(s) Weight: Unknown	2	2	0	Product used: FIPRONIL SPOT ON CAT Other products used: Bob Martin; Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	17-Jun-2019*	2019*	N/A	D-D	As reported by the animal owner, Frankie, a 7-8 year old, male, black cat, (signalment otherwise unknown), and Betty, a 12-14 week old, female, black and white cat (signalment otherwise unknown), were treated with FRONTLINE SPOT ON CAT (batch number: S21204AW, expiry date: AUG 2021), administered topically to the back of the neck, by the animal owner, first administered 8 weeks ago (estimated as 17 JUN 2019), for an unknown indication. The owner reported that since the first application they gave 3 pipettes to each cat within the 8 weeks. Prior to using FRONTLINE, the owner was using a different brand from a large pet retailer every 4 weeks, and before this Bob Martin. At the end of the 4 weeks with the other product, the owner always notices 1 or 2 fleas, but since they have been on FRONTLINE, they have noticed 2-3 every time they pick up the cats. The cats are scratching a lot but the owner is scratching the most, and the owner is being bitten a lot around the ankles/legs. The cats sleep in the owner's bedroom so this is where the owner is being bitten. The owner reported they have vacuumed the house and used flea spray and powder around the house. The owner bought the FRONTLINE from a large online retailer and wondered if the product might be fake. On 06 SEP 2019 QA results were received: Investigation completed for FIPRONIL SPOT ON CAT Lot S21204AW, expiry

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 199 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00206

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											2021-08-31. Final complaint evaluation: A product quality complaint for FRONTLINE SPOT ON CAT, batch number S21204AW, was received by BIAH QA on the 20th of August 2019. The complaint description is: Lack of efficacy and potential counterfeit. This is the first complaint for this batch. The complaint sample is not received and pictures are not attached to this case. The retention sample is not reviewed because it is stored for identification purposes. Therefore, it is not applicable to this kind of defect. Batch records investigation: Batch record review: S212. Manufacturing date: 27/09/2018 - Expiry date:
09-Aug-2019	UAE; 19UK002557; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: 3.00 Week(s) Weight: Unknown	5	5	4	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-A	As reported by the animal owner, a female lactating feline (signalment otherwise unknown) was administered FRONTLINE PLUS SPOT ON CAT (batch and expiry unknown, details unknown) by the animal owner for an unknown indication. The animal owner reports that they put FRONTLINE PLUS on their cat, which had 5 kittens at 3 weeks old, on advice from a shop and now 4 of the kittens have died within the space of 12 hours and the fifth kitten is fighting for it's life. The animal owner doesn't think that this is a coincidence as they were all fit and healthy. They think that this is due to the product. Start date added for submission purposes only.
10-Aug-2019	UAE; 19UK002558; -; United Kingdom	Species: Feline Breed: Feline various breeds Sex: F Sex qualifier: Unknown Age: 8.84 Year(s) Weight: 4 kg	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	Mar-2019*	Apr-2019*	N/A	D-D	As reported by the animal owner, Toffee, an 8 year 10 month old female mixed breed feline weighing 4 kg was administered FRONTLINE (assumed FRONTLINE SPOT ON CAT, batch R21512AX expiry SEP 2020) topically to the back of the neck, by the animal owner, from MAR 2019 at a dose of 1 dose monthly for an unknown indication. The animal owner reports that the animal has continually been scratching and they are finding fleas in the house. The animal owner feels badly let down by the product and it is also not cheap to buy. The animal owner uses the product from Spring to Autumn and the animal has had fleas since APR 2019. People in the home are being bitten, the animal spends time indoors and outdoors and all animals that live in the household and in contact animals have been treated with a flea product. The animal owner is seeing many fleas - 5 or more at the same time, the animal is never bathed nor goes swimming and the animal owner has regularly vacuumed all areas that the pet can access. The owner was desperate to sort out their cat's problem so they changed to Stronghold Plus , as recommended by their vet, and within a few days the problem has gone which suggests that FRONTLINE is useless.
10-Aug-2019	UAE; 19UK002559; -; United Kingdom	Species: Canine Breed: Yorkshire Terrier Sex: F Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: FIPRONIL SPOT ON DOG; Route: unknown Was the product used ok?: Unknown	N/A	29-Jul-2019*	0 Day(s)	D-D	As reported by the animal owner, a female Yorkshire Terrier dog (signalment otherwise unknown), was treated with FRONTLINE ADVANCE (estimated as FRONTLINE PLUS SPOT ON DOG S) and FRONTLINE SPOT ON DOG S, batch numbers and expiry dates unknown, details unknown, by the animal owner, 2 weeks ago (estimated as 29 JUL 2019), for an unknown indication. The owner reported that both times they have treated their dog they have still found fleas on her. The owner is also using the correct weight.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 200 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00207

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
11-Aug-2019	UAE; 19UK002560; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	3	3	0	to Company Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, approximately 3 canines (signalment otherwise unknown) were administered FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG M, batch and expiry unknown, treatment details unknown) for an unknown indication. The animal owner reports that they are most disappointed with the product as the dogs still have fleas. The animal owner reports that they can see from the reviews regarding the product that other customers seem to be saying the same thing. start date for submission purposes only.
11-Aug-2019	UAE; 19UK002561; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: M Sex qualifier: Unknown Age: 8.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	08-Aug-2019	15 Day(s)	D-D	As reported by the animal owner, an 8 year old, male cat (signalment otherwise unknown), was treated with FRONTLINE SPOT ON CAT, details unknown, by the animal owner, all year round, every month, with the last application on 24 JUL 2019, for an unknown indication. The owner reported that the cat has fleas 2 weeks before his next treatment is due. The cat appears quite distressed. The fleas were noticed 4 days ago, with the owner seeing roughly 10 fleas. The owner has also hoovered the house. The cat is an outdoor cat that lives in a town. The owner is not being bitten.
11-Aug-2019	UAE; 19UK002562; -; United Kingdom	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: M Sex qualifier: Unknown Age: 1.00 Year(s) Weight: Unknown	3	3	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, Tiger an 8 year old, Smokie a 6 year old and Lucky a 1 year old, all male Short Hair felines, were administered FRONTLINE SPOT ON CAT (batch s21509bx and SEP 2021) topically by the animal owner to the back of the neck, at a dose of 1 dose every 4 weeks for fleas. The animal owner reports that they bought the product online and it hasn't worked. The animals still have fleas. The animal owner adds that the animals do go outside, they wash their bedding every week and they use the treatment all year round. The animal owner has bites on them, they hoover every day in the house on the bed that they have for the animals and the animals don't wear a collar. Start date added for submission purposes only.
11-Aug-2019	UAE; 19UK002563; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	Jun-2019*	N/A	D-D	As reported by the animal owner, 2 cats (signalment otherwise unknown), were treated with FRONTLINE SPOT ON CAT (batch number and expiry date unknown), details unknown, by the animal owner, regularly, for an unknown indication. The owner reported that they are concerned as for the past few months (estimated as JUN 2019) their cats have had fleas constantly, despite using FRONTLINE. The owner is using it as regularly as they can safely but it isn't working.
12-Aug-2019	UAE; 19UK002564; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: F Sex qualifier: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products	09-Aug-2019	12-Aug-2019	3 Day(s)	D-D	As reported by the animal owner, Cookie, a 2 year old, small, female, Tabby cat, weighing 5 kg, reproductive status unknown, health status unknown, was treated with FRONTLINE PLUS SPOT ON CAT (batch number:S41113AW, expiry date: AUG 2021), details unknown, by the animal owner, on 09 AUG 2019, for an unknown indication. The owner reported that they flea treat their

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 201 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00208

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: 2.00 Year(s) Weight: 5 kg				used: Staykill household flea spray; Route: unknown Was the product used ok?: Yes					pets only over the summer, and only when they have fleas, and have also sprayed the entire house. To date it has had absolutely no effect after first noticing fleas on their cat on 01 JUL 2019, and a flea comb reveals numerous vibrant fleas, with more than 5 fleas being seen at the same time. The owner has used a product distributed by their vet on countless occasions for 20 years with success so its not user-error. The owner reported that they applied the product as specified on the packaging. People in the home are being bitten by the fleas, the cat goes both indoors and outdoors and all animals in the household and all in contact animals have been treated with a flea product. The cat is never bathed, never goes swimming, the owner has lived in their house for more than a year, and they have regularly vacuumed all areas the pets can access, although they have not washed the cats bedding at over 60 degrees Celsius.
12-Aug-2019	UAE; 19UK002566; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	12-Aug-2019	over 48 hours	D-D	As reported by the animal owner, a cat (signalment otherwise unknown), was treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), details unknown, by the animal owner, over 48 hours ago, as a parasiticide against ticks. The owner reported on 12 AUG 2019 that their cat has ticks so the following day they applied FRONTLINE PLUS to kill the ticks. However its been over 48 hours and the ticks are still there.
20-Aug-2019	UAE; 19UK002567; -; United Kingdom	Species: Canine Breed: Bulldog Sex: M Sex qualifier: Unknown Age: 2.00 Year(s) Weight: 46 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: FRONTLINE PETCARE HOME AND ENVIRONMENT FLEA SPRAY; Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	0 Day(s)	D-D	As reported by the animal owner, Mosley, a 2 year old, male, American Bulldog canine, weighing 46 kg (signalment otherwise unknown), was treated with FRONTLINE SPOT ON DOG XL (batch number and expiry date unknown), details unknown, by the animal owner, 3-5 days before the sent the letter (exact date unknown, estimated as 2019), for an unknown indication. The owner reported that they bought 2 products, and it didn't work. The packaging is for 1 of the products. The owner bought one of our Advance treatments that worked. The owner treats the dog with FRONTLINE all year round, whenever they see fleas, and they noticed their current flea issue 8 days before they sent the letter (estimated as 2019). The owner reported that they applied the product as directed, nobody in the house is being bitten by the fleas, the dog spends time indoors and outdoors in the garden, and that Mosley is the only pet in the home and all in contact animals have been treated with a flea product. The owner hasn't seen fleas on their pet but there is flea dirt/evidence of fleas in the dog's fur, the dog is not bathed or goes swimming more than once a week, and this does not occur within 2 days of product administration. The owner has lived in their house for more than a year, has treated it with FRONTLINE PETCARE HOMEGARD HOUSEHOLD FLEA SPRAY (batch number and expiry date unknown), has washed the dogs bedding at over 60 degrees Celsius, and regularly vacuums all areas the dog can access.
10-Aug-2019	UAE; 19UK002570; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: F	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE	N/A	30-Jul-2019	0 Day(s)	D-D	As reported by the animal owner, a female feline (signalment otherwise unknown) was administered FRONTLINE PLUS SPOT ON CAT (batch S41303AW expiry OCT 2021) topically to the back of the neck, by the animal owner at a dose of 1 dose, on 30 JUL

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
 Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
 *indicates Approximate date or weight

Page 202 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00209

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: Unknown Age: - Weight: Unknown				12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company					2019 as they noticed the animal had the odd flea. The animal owner bought a 6 month supply, and after speaking to the assistant in the shop about how to apply correctly they used the spot on on 30 JUL 2019 in the evening and the weather was dry. As the animal has long hair, the animal owner cut a small amount away at the base of the back of her head, above the shoulder blades, to expose a patch of skin. The animal owner then applied the spot on and has also treated all the carpets and furnishings in the house. Unfortunately they are still finding fleas on the animal. The animal owner has 5 more months supply and there is still a couple of weeks until the next treatment. The animal owner is not happy with the result.
12-Aug-2019	UAE; 19UK002572; -; United Kingdom	Species: Canine Breed: Spaniel (Cocker) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	04-Aug-2019	2 Day(s)	D-D	As reported by the animal owner, 2 Cocker Spaniel dogs (signalment otherwise unknown), were treated with FRONTLINE SPOT ON (estimated as FRONTLINE SPOT ON DOG M), batch number and expiry date unknown, details unknown, by the animal owner, on 02 AUG 2019, for an unknown indication. The owner reported that they were advised that it would kill fleas within 24 hours, however 2 days later they are still combing live fleas out of their dogs. They haven't found one dead one. It hasn't done a thing to help. The owner understands about treating the environment which they have done everyday. The owner is taking 20 plus alive fleas off each dog 24 hours after they should of died off.
12-Aug-2019	UAE; 19UK002576; -; United Kingdom	Species: Canine Breed: Large crossbred (>20 Kg) Sex: F Sex qualifier: Unknown Age: 4.00 Year(s) Weight: 22 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	12-Apr-2019	2019*	4 Week(s)	D-D	As reported by the animal owner, Brea, a 4 year old, female, Crossbreed dog, weighing 22 kg (signalment otherwise unknown), was treated with FRONTLINE PLUS SPOT ON DOG L (batch number and expiry date unknown), applied topically to the back of the neck in between the shoulder blades, by the animal owner, every month for 5 months, for an unknown indication. The owner last used the product on 12 APR 2019, 12 MAY 2019, 12 JUN 2019, and on 12 JUL 2019 after noticing their current flea issue 5 months ago. The owner reported that their dog is still getting fleas. They have been using the treatment every month as been told and the dosage is correct for the dog and the owner has been spraying the house to get rid but it seems not to be helping. The owner treats the dog all year round, the dog spends time both indoors and outdoors, and people in the house are being bitten by the fleas. All animals in the household and all in contact animals have been treated with a flea product, the owner is seeing many fleas on their dog, more than 5 at a time, the dog never goes swimming and never gets bathed and therefore is not bathed or goes swimming within 2 days of product application. The owner has lived in their house for less than a year, and has treated the home with an environmental flea spray (product unknown), washed their pet's bedding at over 60 degrees Celsius, and regularly vacuums all area the pets can access. Start date of event added for submission purposes only.
13-Aug-2019	UAE; 19UK002584; -; United Kingdom	Species: Canine Breed: West Highland White Sex: F Sex qualifier: Neutered Age: 7.75 Year(s) Weight: 6.1 kg	2	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical /	N/A	02-Aug-2019	less than 1 hour	D-D	Skin erupted in red sore oozing serum approx 4 x 3 cm less than one hour after product application. Reaction duration one hour. Previously had many treatments with Frontline with out issue.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 203 of 867

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00210

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Cutaneous Was the product used ok?: Unknown to Company					
13-Aug-2019	UAE; 19UK002588; Kent, United Kingdom	Species: Canine Breed: Chihuahua Sex: F Sex qualifier: Neutered Age: 9.00 Year(s) Weight: 3.25 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: FIPRONIL SPOT ON DOG; Apoquel; Route: Topical / Cutaneous Was the product used ok?: Yes	09-Aug-2019	10-Aug-2019*	1 Day(s)	D-D	As reported by the attending veterinary surgeon, Lily, a 9 year old female neutered Chihuahua canine, weighing 3.25 kg and in good condition, was administered FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG S, batch S61716AL expiry JUN 2021) topically to an unknown site, by the animal owner at an unknown dose on 09 AUG 2019 as an antiparasitic. One to two days later (estimated 10 AUG 2019) the animal was running around, jumping up and down, hiding under the bed like she had had an electric shock. The animal's signs resolved but the animal still seems tired. The animal has previously been on FRONTLINE SPOT ON and this was the first dose of FRONTLINE PLUS. The animal has a history of pruritus and is on Apoquel.
13-Aug-2019	UAE; 19UK002589; -, United Kingdom	Species: Canine Breed: Retriever (Golden) Sex: F Sex qualifier: Neutered Age: 5.00 Year(s) Weight: 30 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: FIPRONIL SPOT ON DOG; Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	09-Aug-2019	11-Aug-2019	2 Day(s)	D-D	As reported by the animal owner, Sadie, a 5 year old, neutered, female, Golden Retriever dog, weighing 30 kg and of good health, was treated with FRONTLINE PLUS SPOT ON DOG L (batch number: S63225AL, expiry date: OCT 2021), correctly administered topically to the back of the neck, by the animal owner, on 09 AUG 2019, for an unknown indication. The owner reported that on the Sunday night after application (11 AUG 2019), they noticed that the dog had developed little bumps on its head, neck and ears. They are scabby like sores and vary in size, not big but just little sores. The dog is not irritated by them, not scratching or bothered by them. The dog doesn't like them being examined but she is like that anyway. She hasn't had any treatment yet, and the dog is normal otherwise. The owner had previously used FRONTLINE SPOT ON DOG (assumed L, batch number and expiry date unknown).
13-Aug-2019	UAE; 19UK002590; -, United Kingdom	Species: Canine Breed: Spaniel (English Springer) Sex: M Sex qualifier: Neutered Age: 13.00 Year(s) Weight: 30 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	04-Aug-2019	12-Aug-2019	8 Day(s)	D-D	As reported by the animal owner, Harry, a 13 year old, neutered, male Springer Spaniel dog, weighing 30 kg, and of fair health, was treated with FRONTLINE PLUS SPOT ON DOG L (batch number: S62902AX, expiry date: SEP 2021), correctly administered topically to the back of the neck, by the animal owner, on 04 AUG 2019, for an unknown indication. The owner reported that they found fleas and ticks on Harry and so purchased some FRONTLINE PLUS and applied it on Sunday 04 AUG 2019. By Monday the ticks had died and the fleas were dropping off, it worked really well. However, yesterday (12 AUG 2019) the owner noticed a huge amount of fleas on the dog, they have all come back, with lots on the top of his head. The owner is being bitten on the legs and has seen fleas in the car and on their bedding. The owner has washed every bedding possible and wasn't using any flea treatment prior to the FRONTLINE PLUS because he is elderly and ill and the owner thought it would be best not to give him it. Harry has never had fleas before although he has had ticks. The owner has not used the house spray yet but will go and buy some, they live in a very large house so is worried the spray will not do the whole house. Harry also has Arthritis and is on Pardale.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 204 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00211

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
13-Aug-2019	UAE; 19UK002591; -, United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	06-Aug-2019*	0 Day(s)	D-D	As reported by the animal owner, approximately 2 dogs (signalment otherwise unknown), were treated with FRONTLINE PLUS (estimated as FRONTLINE PLUS SPOT ON DOG M), batch number and expiry date unknown, details unknown, by the animal owner, 1 week ago (06 AUG 2019), for an unknown indication. The owner reported that they bought FRONTLINE PLUS for their dogs and cats a week ago and the product has done nothing to resolve the flea issue at all. Start date of event added for submission purposes only. Case linked to case 19UK002592.
13-Aug-2019	UAE; 19UK002592; -, United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	06-Aug-2019*	0 Day(s)	D-D	As reported by the animal owner, approximately 2 cats (signalment otherwise unknown), were treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), details unknown, by the animal owner, 1 week ago (06 AUG 2019), for an unknown indication. The owner reported that they bought FRONTLINE PLUS for their dogs and cats a week ago and the product has done nothing to resolve the flea issue at all. Start date of event added for submission purposes only. Case linked to case 19UK002591.
13-Aug-2019	UAE; 19UK002593; Gloucestershire; United Kingdom	Species: Canine Breed: Yorkshire Terrier Sex: F Sex qualifier: Neutered Age: 13.00 Year(s) Weight: 4.8 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	N/A	2019*	N/A	D-D	As reported by a member of the veterinary clinic staff, Jofie, a 13 year old, neutered, female, Yorkshire Terrier dog, weighing 4.8 kg and of good health, was treated with FRONTLINE (estimated as FRONTLINE SPOT ON DOG S), batch number and expiry date unknown, correctly administered, by the animal owner, monthly, exact dates unknown, for an unknown indication. The member of staff reported that the owner feels the product hasn't worked. The owners are not being bitten and the home hasn't been treated. Start date of event added for submission purposes only.
13-Aug-2019	UAE; 19UK002594; -, United Kingdom	Species: Canine Breed: French Bulldog Sex: M Sex qualifier: - Age: 3.00 Year(s) Weight: 15.2 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	N/A	05-Aug-2019	5 Day(s)	D-B	Dog administered Frontline Plus Spot-on Dog M reacted starting about 5 days later. Local reaction to where product applied at base of neck, 2 x 3" patch of skin very red, inflamed, deeper part a bit of fibrin/necrotic/exudate over 1", painful, probably infected. Previous exposure with no reaction.
13-Aug-2019	UAE; 19UK002599; -, United Kingdom	Species: Feline Breed: Feline (unknown)	2	1	1	Product used: FIPRONIL 10%/S METHOPRENE	N/A	2019*	N/A	D-A	As reported by the animal owner, 2 cats (estimated, signalment otherwise unknown), were treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), details unknown, by the animal owner, on an unknown date, for an

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 205 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00212

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex: U Sex qualifier: Unknown Age: - Weight: Unknown				12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company					unknown indication. The owner reported that they have 2 FRONTLINE PLUS delivered to their house, however needs to cancel one of them as one of their cats has died. Start date of event added for submission purposes only.
13-Aug-2019	UAE; 19UK002601; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	May-2019*	20-Jun-2019*	N/A	D-D	As reported by the animal owner, 2 dogs in good health (signalment otherwise unknown), were treated with FRONTLINE PLUS (estimated as FRONTLINE PLUS SPOT ON DOG M), batch number and expiry date unknown, applied topically to the back of the neck, by the animal owner, with 3 pipettes used on each dog over a 2 month period, for an unknown indication. The owner reported that they first applied the FRONTLINE PLUS at the end of MAY 2019 and noticed fleas 3-4 weeks later so applied the 2nd pipette on each dog on 20 JUL 2019. On 05 AUG 2019 they noticed one dog has fleas all over him and both dogs have had ticks throughout. The owner used the last of their supply today (05 AUG 2019) because of the fleas. The owner reported that they used the treatment the correct way but for some reason had no positive results this year. Recently the owner went to the vets as was not happy with the FRONTLINE and got a different product which has sorted out the problem (estimated as AUG 2019). The owner is not being bitten in the house but has seen a few fleas around the house. They are seeing more than 5 fleas on each dog. Prior to the first application of FRONTLINE PLUS, they were using different flea products and collars. The owner does not use the treatment during the winter as there is no point, and they have chucked out the dogs bedding and have purchased home spray to use.
13-Aug-2019	UAE; 19UK002602; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: F Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	13-Aug-2019	3 Day(s)	D-D	As reported by the animal owner, a female dog (signalment otherwise unknown), was treated with FRONTLINE SPOT ON DOG S (batch number and expiry date unknown), details unknown, by the animal owner, on 10 AUG 2019, for an unknown indication. The owner reported that they have found 2 dead ticks since application which is great, but this morning (13 AUG 2019) they found a large engorged tick feeding in the dog's neck which they had to remove with a tick remover. The owner is a vet nurse and their understanding is that the tick shouldn't have to bite to die and should be killed by coat/skin contact.
13-Aug-2019	UAE; 19UK002603; -; United Kingdom	Species: Canine Breed: Small crossbred (<10 Kg) Sex: X Sex qualifier: Unknown Age: 6.00 Year(s) Weight: 7 - 8 kg	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown	N/A	06-Aug-2019	1 Week(s)	D-D	As reported by the animal owner, Jack, an 8 year old, male, Jack Russell Terrier dog, weighing 8 kg (signalment otherwise unknown), and Poppy, a 6 year old, female, Cross Breed Terrier dog, weighing 7 kg (signalment otherwise unknown) were treated with FRONTLINE PLUS SPOT ON DOG S (batch number: S62713AW, expiry date: SEP 2021), applied topically to the neck, by the animal owner, for some time, all year round, as prescribed on a regular basis, with the last application 3 weeks ago (estimated as 30 JUL 2019), for an unknown indication. The owner reported that at the moment both dogs are being plagued by fleas. The owner has taken all the usual precautions but still they will not go away, and they have consulted their vets who have told them that fleas are now immune to the product. The owner reported that 2

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 206 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00213

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						to Company					weeks ago (06 AUG 2019) they first noticed their current flea issue. The owner reported that people in the house are not being bitten, the dogs spend time both indoors and outdoors, all animals in the home as well as all in contact animals have been treated with a flea product, and they are only finding occasional fleas on their pets, less than 5 at the same time. The pets don't get bathed or go swimming more than once a week, and this does not occur within 2 days of product administration. The owner has lived in their house for 50 years, and has treated their home with an environmental flea treatment, has washed all of their pet's bedding at over 60 degrees Celsius and has regularly vacuumed all areas the pets can access.
13-Aug-2019	UAE; 19UK002604; -, United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	13-Aug-2019	6 Day(s)	D-D	As reported by the animal owner, 2 dogs (signalment otherwise unknown), were treated with FRONTLINE PLUS (estimated as FRONTLINE PLUS SPOT ON DOG M), batch number and expiry date unknown, details unknown, by the animal owner, just under a week ago (estimated as 7 AUG 2019), for an unknown indication. The owner reported that both dogs are still flea ridden.
13-Aug-2019	UAE; 19UK002607; -, United Kingdom	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: F Sex qualifier: Neutered Age: 12.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	N/A	Aug-2018*	approximately 10 minutes	D-C	As reported by the animal owner, Molly, a 12 year old, neutered, female, Domestic Shorthair cat, described as tiny, of good health, exact weight unknown, was treated with FRONTLINE (estimated as FRONTLINE SPOT ON CAT), batch number and expiry date unknown, details unknown, by the animal owner, over a year ago, with the last application a year ago, for an unknown indication. The owner reported that the cat goes rather loopy for about 24 hours after FRONTLINE is applied, and has large pupils and acts as if it has been given a dose of catnip. The cat went to the vets after its last treatment a year ago and the owner stated that she was concerned about her cat goes rather loopy, but the vet said there is really no other option to treat the cat. Every time the FRONTLINE was applied the cat would become strange, with the pupils enlarged and nutty for around 24 hours, and this would begin very quickly after the application, maybe 10 minutes after. They don't think its related but was like this after an anaesthetic (no further details provided). The vets never saw the cat. The owner hasn't used FRONTLINE or any other flea treatment since due to the reactions.
13-Aug-2019	UAE; 19UK002610; -, United Kingdom	Species: Canine Breed: Shih Tzu Sex: F Sex qualifier: Unknown Age: 7.50 Year(s) Weight: 7 - 9 kg	2	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	12-Aug-2019	2 Week(s)	D-D	As reported by the animal owner, Speckle weighing approximately 9 kg, and Sparkle weighing approximately 7 kg, two female Shih Tzu dogs aged 7.5 years, were treated with FRONTLINE PLUS SPOT ON DOG S (batch number: S60328AL, expiry date: JAN 2021), details unknown, by the animal owner, on 29 JUL 2019, for an unknown indication. The owner reported that they discovered a flea on one of the dogs on 12 AUG 2019, so they assume that the batch is faulty. The animal owner adds that the product has been ineffective. The animal owner uses the product when they see fleas only over the summer and started using the product for the current flea issue on 29 JUL 2019. They first noticed the fleas on the pet on 28 JUL 2019 and applied the product as per the instructions. No one in the home is being bitten and the animals

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 207 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00214

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											<p>spend time both indoors and outdoors. All animals in the household and in contact animals have been treated and the animal owner is seeing occasional fleas - less than 5 at the same time. The animals are bathed or go swimming no more than once a week and the animal owner has treated the home with an environmental flea treatment, washed the pet's bedding at over 60 degrees and regularly vacuumed all areas that the pets can access. The animal owner reports that their vet does not recommend FRONTLINE at all and certainly not as a preventative measure. The animal owner states that they will never buy the product again.</p> <p>On 06 SEP 2019 QA results were received: Investigation completed for FIPRONIL 10%/S METHOPRENE 9% SPOT ON Lot S60328AL, expiry 2021-01-31. Final complaint evaluation: A product quality complaint for FRONTLINE PLUS SPOT ON DOGS S, batch number S60328AL, was received by BIAH QA on the 22th of August 2019. The complaint description is: Lack of efficacy. This is the second complaint for this batch regarding this kind of defect. The complaint sample is not received but pictures are attached to this case. The retention sample is not reviewed because it is</p>
13-Aug-2019	UAE; 19UK002611; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	Aug-2019*	N/A	D-D	<p>As reported by the animal owner, two canines (signalment otherwise unknown) were administered FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG M, batch, expiry and further details unknown) by the animal owner for many years for an unknown indication. The animal owner reports that they took their dog to the vets last week as he had started to chew its foot. The animal owner was told by the vet that FRONTLINE was no longer working on animals as fleas etc had become immune to the product and it was not as effective any more. The animal owner ended up buying a tablet from the vet that will last in their system for three months. The animal owner also has a cat which has also received FRONTLINE PLUS for many years.</p>
14-Aug-2019	UAE; 19UK002613; -; United Kingdom	Species: Canine Breed: Schnauzer (Miniature) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: FRONTLINE PETCARE HOME AND ENVIRONMENT FLEA SPRAY; Route: unknown Was the product used ok?: Unknown to Company	N/A	14-Aug-2019	2 Day(s)	D-D	<p>As reported by the animal owner, 2 miniature Schnauzer dogs (signalment otherwise unknown) were treated with FRONTLINE PLUS (estimated to be FRONTLINE PLUS SPOT ON DOGS M) batch number and expiry date unknown, route and frequency unknown, administered by the dog's owner on 12 AUG 2019. The owner was advised by a retailer to buy FRONTLINE PLUS SPOT ON treatment and household spray (assumed FRONTLINE PETCARE HOMEGARD HOUSEHOLD FLEA SPRAY). On Monday (12 AUG 2019) the owner used the treatments on the dogs and thoroughly vacuumed all areas the dogs have access to and used the house spray. On 14 AUG 2019 the owner reported that the 2 dogs were still full of fleas.</p>
14-Aug-2019	UAE; 19UK002617; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE	N/A	01-Aug-2019*	0 Day(s)	D-D	<p>As reported by the animal owner, approximately 2 dogs (signalment otherwise unknown), were treated with FRONTLINE PLUS (estimated as FRONTLINE PLUS SPOT ON DOG M), batch number and expiry date unknown, details unknown, by the animal owner, on 01 AUG 2019, for an unknown indication. The owner</p>

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
 Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
 *indicates Approximate date or weight

Page 208 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).
 Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.
 Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00215

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: Unknown Age: - Weight: Unknown				9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company					reported that sadly their dogs still have fleas. Start date of event added for submission purposes only.
14-Aug-2019	UAE; 19UK002619; -, United Kingdom	Species: Canine Breed: Canine Other: Sex: M Sex qualifier: Neutered Age: 8.00 Year(s) Weight: 28 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: Unspecified house spray; Route: Topical / Cutaneous Was the product used ok?: Yes	N/A	14-Aug-2019	2 Day(s)	D-D	As reported by the animal owner, Rudy, an 8 year old male neutered Rough Collie canine, weighing 28 kg and in unknown condition, was treated with FRONTLINE PLUS (estimated as FRONTLINE PLUS SPOT ON DOGS M) batch number S63101BX and expiry date SEP 2021, topically to the back of the neck by the animal owner, last applied by the dog's owner on 12 AUG 2019 (the owner reported that they applied it every 30 days). The owner reported on 14 AUG 2019 that they had seen 7 or 8 fleas this week they were very unhappy with the product. The owner hoovered and dusted all the time. They did not have carpets but had floor and tiles, so they thought the fleas would not survive in the house. The owner also reported that they had one of the best house sprays on the market. They had used FRONTLINE PLUS in the past on another dog and seen the fleas die straight away, not over 24 hours as stated on the box. The animal owner added that they are not happy with the product as they have used it on the dog and he still has fleas - they are only seeing a few but the packaging says it will kill them within 24 hours and so asks why they are still seeing fleas. Their husband used FRONTLINE on their dog years ago and it worked - killed the fleas immediately - and the animal owner is guessing that there is a change in the ingredients as it doesn't kill the fleas anymore. The animal owner used a different brand before this one and it worked but saw FRONTLINE PLUS thinking it had better ingredients in, and got it and put in on their animal. The animal owner adds that they don't have carpet and are not using a home spray on their leather sofas. They have laminate flooring and tiles, all close together so no fleas can get in there. The animal owner did not take the animal for a walk and only allowed him in the garden one day and that has only concrete so there are no fleas in the garden.
14-Aug-2019	UAE; 19UK002620; -, United Kingdom	Species: Canine Breed: Canine various breeds Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: Bob Martin; Johnsons Flea Spray; Route: unknown Was the product used ok?: No (Treatment / vaccination program not respected)	Feb-2019*	2019*	2 Day(s)	D-D	As reported by the animal owner, Ted, a male mongrel dog (signalment otherwise unknown), was treated with FRONTLINE SPOT ON (estimated as FRONTLINE SPOT ON DOG M), batch number and expiry date unknown, details unknown, by the animal owner, every 3 weeks since FEB 2019, with the last application on 12 AUG 2019, for an unknown indication. The owner reported that FRONTLINE doesn't work. The owner's dog groomer said that FRONTLINE doesn't work any more however the owner thinks they might be trying to mug them off and sell them their product instead. The owner has used Bob Martin once, the dog does not go swimming but is washed at the dog groomers or when it is dirty, and they live in the countryside. The owner has sprayed Johnsons flea stuff on the house. They are finding 3 fleas on the dog and loads of flea dirt. The owner is not being bitten by the fleas. Start date of event added for submission purposes only.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 209 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00216

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
14-Aug-2019	UAE; 19UK002625; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	3	3	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, 3 cats (signalment otherwise unknown), were treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), details unknown, by the animal owner, on an unknown date, for an unknown indication. The owner reported that all 3 cats still have fleas. Start date of event added for submission purposes only.
14-Aug-2019	UAE; 19UK002626; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a male dog (signalment otherwise unknown), was treated with FRONTLINE PLUS SPOT ON DOG (estimated as FRONTLINE PLUS SPOT ON DOG M), batch number and expiry date unknown, details unknown, by the animal owner, on an unknown date, for an unknown indication. The owner reported that after using FRONTLINE PLUS SPOT ON DOG, he still has fleas. Start date of event added for submission purposes only.
14-Aug-2019	UAE; 19UK002628; -; United Kingdom	Species: Feline Breed: Birman Sex: U Sex qualifier: Unknown Age: 10.00 Year(s) Weight: 3 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	N/A	Aug-2019*	3 Week(s)	D-D	As reported by the animal owner, Saffron, a 10 year old, Birman cat, sex and reproductive status unknown, weighing 3 kg and in good health, was treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), correctly applied topically to the back of the neck, by the animal owner, 2-3 weeks ago (estimated as 01 AUG 2019), for an unknown indication. The owner reported that they used FRONTLINE PLUS 2 to 3 weeks ago but they are still seeing fleas, not a great deal though. The owner is going to continue using the product as stated. Start date of event added for submission purposes only.
14-Aug-2019	UAE; 19UK002630; -; United Kingdom	Species: Canine Breed: Greyhound Sex: F Sex qualifier: Neutered Age: 9.00 Year(s) Weight: 33 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	Oct-2018*	May-2019*	N/A	D-D	As reported by the animal owner, Missy, a 9 year old, neutered, female Greyhound dog, weighing 33 kg and of good health, was treated with FRONTLINE PLUS SPOT ON DOG L (batch number: S60626, batch number: FEB 2021), correctly administered topically to the back of the neck, by the animal owner, monthly, for 10 months, for an unknown indication. The owner reported that FRONTLINE PLUS has been applied to their 6 cats and 1 dog every month for the last 10 months. No fleas have been seen on the cats and they do not seem to be affected, however the dog is riddled with fleas. The fleas were first noticed 3 months ago on the dog and the problem has just been getting worse. The owner just washed the dog off in the bath and lots of huge fleas were falling off him as well as lots of flea dirt, and lots of streaks of blood were in the bath. The owner also reported that family members are being bitten, her son has so many bites round his ankles and she also had a few bites but not as many. The owner confirmed that

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 210 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00217

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											there has definitely not been any gaps between treatment and the dog doesn't usually get bathed or swim or wear a collar. The house has been sprayed with treatment. The dog also goes to the horse yard with the owner every day. The owner has taken the day off work to blitz the house and carry out all the home infestation treatment methods, and she was quite unhappy/distressed about the whole situation.
14-Aug-2019	UAE; 19UK002632; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	3	3	0	Product used: FIPRONIL SPOT ON CAT Other products used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON; Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	0 Day(s)	D-D	As reported by the animal owner, 3 cats (signalment otherwise unknown) were treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), details unknown, by the animal owner, recently, for an unknown indication. The owner reported that they have 3 cats and 2 dogs, a Cocker Spaniel and a Bull Mastiff, and that they have been using FRONTLINE for a while. The owner recently noticed that there were fleas on the cats and so purchased FRONTLINE PLUS instead. They bought a pack of FRONTLINE PLUS SPOT ON CAT and a pack of 20 kg for the Cocker Spaniel and then the small dog pack and the large dog pack for their Mastiff. They reported that the product does not work at all. The owner reported that the product has been applied correctly and when they had to take them to the vets who informed them that FRONTLINE doesn't work anymore. The owner also spoke to a local pets controller who confirmed that the vet was correct and FRONTLINE does not work. Case linked to 19UK002633 and 19UK002634
14-Aug-2019	UAE; 19UK002633; -; United Kingdom	Species: Canine Breed: Spaniel (Cocker) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON; Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a Cocker Spaniel dog (signalment otherwise unknown) was treated with FRONTLINE PLUS SPOT ON 20 KG (estimated as FRONTLINE PLUS SPOT ON DOG M, batch number and expiry date unknown), details unknown, by the animal owner, recently, for an unknown indication. The owner reported that they have 3 cats and 2 dogs, a Cocker Spaniel and a Bull Mastiff, and that they have been using FRONTLINE for a while. The owner recently noticed that there were fleas on the cats and so purchased FRONTLINE PLUS instead. They bought a pack of FRONTLINE PLUS SPOT ON CAT and a pack of 20 kg for the Cocker Spaniel and then the small dog pack and the large dog pack for their Mastiff. They reported that the product does not work at all. The owner reported that the product has been applied correctly and when they had to take them to the vets who informed them that FRONTLINE doesn't work anymore. The owner also spoke to a local pets controller who confirmed that the vet was correct and FRONTLINE does not work. Case linked to 19UK002632 and 19UK002634
14-Aug-2019	UAE; 19UK002634; -; United Kingdom	Species: Canine Breed: Bull-Mastiff Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON; FIPRONIL SPOT ON DOG; Route: unknown	N/A	2019*	0 Day(s)	D-D	As reported by the animal owner, a Bull-Mastiff dog (signalment otherwise unknown) was treated with FRONTLINE PLUS SPOT ON L (batch number, expiry date and details unknown) and FRONTLINE PLUS SPOT ON S (batch number, expiry date and details unknown) by the animal owner, recently, for an unknown indication. The owner reported that they have 3 cats and 2 dogs, a Cocker Spaniel and a Bull Mastiff, and that they have been using FRONTLINE for a while. The owner recently noticed that there were fleas on the cats and so purchased FRONTLINE PLUS instead (linked case 19UK002632). They bought a pack of FRONTLINE PLUS SPOT ON CAT and a pack of 20 kg for the Cocker Spaniel (linked case 19UK002633) and then the small dog pack (FRONTLINE PLUS SPOT ON DOG S) and the large dog pack (FRONTLINE PLUS SPOT ON DOG L) for their Mastiff. They

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 211 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00218

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Was the product used ok?: Unknown to Company					reported that the product does not work at all. The owner reported that the product has been applied correctly and when they had to take them to the vets they informed them that no, FRONTLINE doesn't work anymore. The owner also spoke to a local pets controller who confirmed that the vet was correct and FRONTLINE does not work. UPDATE 17 SEP 2019: Following internal review, was product used correctly box was completed (ticked unknown) for FRONTLINE SPOT ON DOG M (which is the product the animal is assumed to have received prior to FRONTLINE PLUS).
15-Aug-2019	UAE; 19UK002637; -; United Kingdom	Species: Feline Breed: British Shorthair Sex: F Sex qualifier: Neutered Age: 9.00 Year(s) Weight: 6 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	May-2019*	15-Aug-2019	1 Week(s)	D-D	As reported by the animal owner, Penny, a 9 year old, neutered, female, British Blue cat, weighing 6 kg, and of good health, was treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), applied topically to the back of the neck, by the animal owner, on 08 AUG 2019, after the owner saw fleas. The owner reported that the cat is an inside cat and has seen what she believes to be a flea this morning, not on the cat but in the bed where she sleeps. The cat is also itching and generally a bit uncomfortable, and the owner has been bitten several times. The owner has sprayed the house with a pesticide spray. The owner reported that they have been using FRONTLINE PLUS for the last 3 or 4 months but haven't been using it every month as there were some gaps in between.
15-Aug-2019	UAE; 19UK002638; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: FIPRONIL SPOT ON DOG; Route: unknown Was the product used ok?: Unknown to Company	08-Aug-2019*	15-Aug-2019	1 Week(s)	D-D	As reported by the animal owner, a dog (signalment otherwise unknown), was treated with FRONTLINE PLUS (estimated as FRONTLINE PLUS SPOT ON DOGS M), batch number and expiry date unknown, route and frequency unknown, administered by the owner a week ago (date estimated as 08 AUG 2019). The owner reported a week later on 15 AUG 2019 that the product had absolutely no effect and the owner felt let down by the product. They had been using FRONTLINE (estimated as FRONTLINE PLUS SPOT ON DOGS M, batch number and expiry date unknown, route and frequency unknown) on their dog and cat for many years but had bought FRONTLINE PLUS a week ago for both the cat and dog and it had not worked (linked case 19UK002639). No further information was supplied.
15-Aug-2019	UAE; 19UK002639; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: FIPRONIL SPOT ON CAT; Route: unknown Was the product used ok?: Unknown to Company	08-Aug-2019*	15-Aug-2019	1 Week(s)	D-D	As reported by the animal owner, a cat (signalment otherwise unknown), was treated with FRONTLINE PLUS SPOT ON CATS (batch number and expiry date unknown), route and frequency unknown, administered by the owner a week ago (date estimated as 08 AUG 2019). The owner reported a week later on 15 AUG 2019 that the product had absolutely no effect and the owner felt let down by the product. They had been using FRONTLINE on their dog and cat for many years but had bought FRONTLINE PLUS a week ago for both the cat and dog and it had not worked (linked case 19UK002638). No further information was supplied.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 212 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00219

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
15-Aug-2019	UAE; 19UK002641; Wiltshire; United Kingdom	Species: Feline Breed: Feline Other Sex: M Sex qualifier: Unknown Age: 11.00 Year(s) Weight: 3.8 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	Apr-2019*	04-Jul-2019	N/A	D-D	As reported by the animal owner, Gremlin, an 11 year old, male neutered tabby cat weighing 3.8 kg (signalment otherwise unknown), was treated with FRONTLINE PLUS SPOT ON CAT (batch number: S41303AW and expiry date: OCT 2021), 1 pipette used (route unknown), administered by the owner from APR 2019, for parasitic control. The animal was also treated on 02 JUL 2019. The owner noticed a couple of days later (date estimated as 04 JUL 2019) that the cat was scratching, so the owner thought the preparation had not yet become effective, but from previous experience the owner thought this was unusual. After much deliberation the owner treated the cat again with 1 pipette of FRONTLINE PLUS SPOT ON CAT. Some days later the owner noticed the cat was still scratching and on closer examination it was evident that the cat was still troubled with parasites. This was confirmed after a visit to the veterinary practitioner on 31 JUL 2019. The owner was then forced to question the batch of the medication. The animal owner applied the product again on 24 JUL 2019, each time as per the instructions and that they have used the product before. People in the home are not being bitten, the animal spends time indoors and outdoors and the animal owner is seeing occasional fleas - less than 5 fleas at the same time. The animal is never bathed nor goes swimming, the animal owner has treated the home with an environmental flea treatment and regularly vacuumed all areas that the pet can access.
15-Aug-2019	UAE; 19UK002642; -; United Kingdom	Species: Canine Breed: Border Collie Sex: M Sex qualifier: Unknown Age: 11.00 Year(s) Weight: 27 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: FRONTLINE PETCARE HOME AND ENVIRONMENT FLEA SPRAY; Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	2008*	Apr-2019	N/A	D-D	As reported by the animal owner, Ben, an 11 year old, male Border Collie dog, weighing 27 kg (signalment otherwise unknown), was treated with FRONTLINE SPOT ON DOG L (batch number and expiry date unknown), administered topically to an unknown site, by the animal owner, monthly, all year round, with the last applications on 01 MAY 2019, 01 JUN 2019, 01 JUL 2019, 01 AUG 2019, as a prophylactic treatment. The owner reported that they have been a loyal user of FRONTLINE DOG and FRONTLINE CAT for over 12 years. They have never missed a month of treatment, with the pets treated all year round, for their 3 dogs (see linked case 19UK002644) and their cat but now they have 2 dogs with fleas (the identity of the affected dogs is not known so has been estimated), with the fleas first noticed in APR 2019. The owner was advised by their vet that the fleas have built up immunity to FRONTLINE. The owner reported that they have a home infestation for 2 months now (started JUN 2019) and that 4 cans of FRONTLINE PETCARE HOMEGARD HOUSEHOLD FLEA SPRAY (batch number and expiry date unknown), have been used. The owner has no carpets on the ground floor of their house and the dogs are combed daily now and they still have live fleas. None of the owner's pets have had fleas until this year, no one in the house is being bitten by the fleas, all animals in the household and all in contact animals have been treated with a flea product, and the owner is seeing many fleas, more than 5 at the same time. The owner's pets don't get bathed or go swimming more than once a week, and when they do this does not occur within 2 days of product administration. The owner has lived in their house for over a year, has treated it with an environmental flea spray, has washed all the pet's bedding at over 60 degrees Celsius, and regularly vacuums all areas the pets can access. The owner also reported that they have now had to get a prescription for Advocate to control this from their vet.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 213 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00220

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
15-Aug-2019	UAE; 19UK002644; -; United Kingdom	Species: Canine Breed: Canine various breeds Sex: X Sex qualifier: Unknown Age: 6.00 Year(s) Weight: 17.9 - 20.8 kg	2	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: FRONTLINE PETCARE HOME AND ENVIRONMENT FLEA SPRAY; Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	2011*	Apr-2019*	N/A	D-D	As reported by the animal owner, Bess, an 8 year old, female, Rough Collie dog, weighing 20.8 kg (signalment otherwise unknown), and Harris, a 6 year old, male, Working Cocker Spaniel dog, weighing 17.9 kg (signalment otherwise unknown), were treated with FRONTLINE SPOT ON DOG M (batch number and expiry date unknown), administered topically to an unknown site, by the animal owner, monthly, all year round, with the last applications on 01 MAY 2019, 01 JUN 2019, 01 JUL 2019, 01 AUG 2019, as a prophylactic treatment. The owner reported that they have been a loyal user of FRONTLINE DOG and FRONTLINE CAT for over 12 years. They have never missed a month of treatment, with the pets treated all year round, for their 3 dogs and their cat but now they have 2 dogs with fleas (the identity of the affected animals is unknown so it is estimated that one animal from this case and 1 animal from linked case 19UK002642 were affected), with the fleas first noticed in APR 2019. The owner was advised by their vet that the fleas have built up immunity to FRONTLINE. The owner reported that they have a home infestation for 2 months now (started JUN 2019) and that 4 cans of FRONTLINE PETCARE HOMEGARD HOUSEHOLD FLEA SPRAY (batch number and expiry date unknown), have been used. The owner has no carpets on the ground floor of their house and the dogs are combed daily now and they still have live fleas. None of the owner's pets have had fleas until this year, no one in the house is being bitten by the fleas, all animals in the household and all in contact animals have been treated with a flea product, and the owner is seeing many fleas, more than 5 at the same time. The owner's pets don't get bathed or go swimming more than once a week, and when they do this does not occur within 2 days of product administration. The owner has lived in their house for over a year, has treated it with an environmental flea spray, has washed all the pet's bedding at over 60 degrees Celsius, and regularly
15-Aug-2019	UAE; 19UK002647; -; United Kingdom	Species: Canine Breed: Staffordshire Terrier (American) Sex: F Sex qualifier: Unknown Age: 9.00 Year(s) Weight: 28.58 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	01-Aug-2019	Aug-2019*	1 Day(s)	D-D	As reported by the animal owner, Sissy, a 9 year old, intact, female, Staffordshire Bull Terrier dog, weighing 28.58 kg, and of good health, was treated with FRONTLINE PLUS SPOT ON DOG L (batch number and expiry date unknown), applied topically to an unknown site, by the animal owner, on 01 AUG 2019 and again on 15 AUG 2019, as a parasiticide. The owner reported that the dog developed itchy skin and had an allergy to the flea saliva. A nit comb was used on the dog. The owner also has 3 cats, which were all treated with FRONTLINE PLUS to the same treatment schedule as the dog. The owner's daughter has been bitten loads and they have a suspected home infestation. Case linked to 19UK002648.
15-Aug-2019	UAE; 19UK002648; -; United Kingdom	Species: Feline Breed: Feline various breeds Sex: U Sex qualifier: Unknown Age: -	3	3	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other	01-Aug-2019	Aug-2019*	1 Day(s)	D-D	As reported by the animal owner, a Tabby cat, a Tortoiseshell cat, and a black Kitten (signalment otherwise unknown), were treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), applied topically to an unknown site, by the animal owner, on 01 AUG 2019 and again on 15 AUG 2019, as a parasiticide. The owner reported that the dog developed itchy skin and had an allergy to the flea saliva. A nit comb was used on the

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 214 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00221

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: Unknown				products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)					dog. The owner also applied FRONTLINE PLUS to the 3 cats, which were all treated with FRONTLINE PLUS to the same treatment schedule as the dog, with the kitten treated by the vet and the other 2 treated by an unknown individual. The owner's daughter has been bitten loads and they have a suspected home infestation. Case linked to 19UK002647.
15-Aug-2019	UAE; 19UK002649; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	13-Aug-2019*	0 Day(s)	D-D	As reported by the animal owner, a dog (signalment otherwise unknown), was treated with FRONTLINE (estimated as FRONTLINE SPOT ON DOG M), batch number and expiry date unknown, details unknown, by the animal owner, over 48 hours ago (estimated as 13 AUG 2019), for an unknown indication. The owner reported that their dog has recently been suffering with a flea problem. The pack was purchased from a large supermarket a few days ago and was the correct dosage for their dog's weight. The owner reported that they applied the product exactly as per the instructions. Over 48 hours later their dog is still suffering with fleas, so it doesn't appear to be working at all. The owner reported that they are now going to have to purchase other treatments.
15-Aug-2019	UAE; 19UK002651; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: M Sex qualifier: Unknown Age: 12.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: No (Treatment / vaccination program not respected)	26-Jul-2019	2019*	8 Day(s)	D-D	As reported by the animal owner, a 12 year old, male cat (signalment otherwise unknown), was treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), details unknown, by the animal owner, on 26 JUL 2019 and again on 08 AUG 2019, for an unknown indication. The owner reported that the FRONTLINE PLUS SPOT ON CAT hasn't worked. The cat hadn't had any treatment of anything the month prior and that's when he picked up fleas. People in the home are being bitten and the owner has treated the house. 5-6 fleas are being seen on the cat each time they comb him, and little white eggs. The cat has been shampooed in between treatment and the product was not applied when is was wearing a collar. The cat has now been quarantined in one room.
15-Aug-2019	UAE; 19UK002653; -; United Kingdom	Species: Canine Breed: Canine various breeds Sex: X Sex qualifier: Unknown Age: 6.00 Year(s) Weight: 18 kg*	2	2	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	N/A	27-Jul-2019*	0 Day(s)	D-D	As reported by the animal owner, Ruby, a 12 year old, female, Pugalier dog, weighing approximately 18 kg, reproductive status unknown, and of good health, and Arthur, a 6 year old, male, Staffordshire Bull Terrier dog, weighing approximately 18 kg, reproductive status unknown, and of good health, were treated with FRONTLINE SPOT ON DOG M (batch number and expiry date unknown), correctly applied topically to the back of the neck, by the animal owner, on 27 JUL 2019, as a parasiticide. The owner reported that back in JUL 2019 she had seen fleas on her dogs for the first time, and so treated them on 27 JUL 2019. The owner is still seeing fleas and the product is doing absolutely nothing. Both dogs had not been treated prior to this. The owner is currently using a home spray
15-Aug-2019	UAE; 19UK002654; -; United Kingdom	Species: Feline Breed: Feline Other Sex: M	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products	04-Jul-2019*	04-Jul-2019*	N/A	D-D	As reported by the animal owner, Mowser, a 16 year old male neutered Domestic Black and White feline, of unknown weight and in good condition, was administered FRONTLINE SPOT ON CAT (batch S21204BW expiry unknown) topically to an unknown site,

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 215 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00222

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: Neutered Age: 16.00 Year(s) Weight: Unknown				used: FRONTLINE PETCARE HOME AND ENVIRONMENT FLEA SPRAY; Route: Topical / Cutaneous Was the product used ok?: Yes					by the animal owner, at a dose of 1 pipette from 6 weeks ago as they saw fleas. The animal owner reported that the animal had fleas a couple of weeks ago, so they purchased FRONTLINE SPOT ON. They are still seeing fleas. The animal owner was previously using Bob Martin but has had some treatment gaps throughout the year. The animal owner is currently treating the house with FRONTLINE PETCARE HOMEGARD HOUSEHOLD FLEA SPRAY (batch and expiry unknown). They are not being bitten.
15-Aug-2019	UAE; 19UK002655; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a male dog (signalment otherwise unknown), was treated with FRONTLINE PLUS (estimated as FRONTLINE PLUS SPOT ON DOG M), batch number and expiry date unknown, details unknown, by the animal owner, on an unknown date for an unknown indication. The owner reported that their dog has fleas and they use FRONTLINE PLUS. Their poor dog is scratching himself terribly. The owner has used the flea comb and is still finding fleas on him. Start date of event added for submission purposes only.
16-Aug-2019	UAE; 19UK002659; -; United Kingdom	Species: Canine Breed: French Bulldog Sex: F Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	15-Aug-2019	6 Week(s) 3 Day(s)	D-D	As reported by the animal owner, a female, French Bulldog canine (signalment otherwise unknown), was treated with FRONTLINE SPOT ON (estimated as FRONTLINE SPOT ON DOG M), batch number and expiry date unknown, details unknown, by the animal owner, on 01 JUL 2019, for an unknown indication. The owner reported that last night (15 AUG 2019, 46 days following product administration) they found a flea on the dog. There is no flea residue or anything on her bedding or crawling through her fur, just this one bug. The owner has never encountered this problem before and the dog hasn't socialised with any other dogs or any other animals.
16-Aug-2019	UAE; 19UK002660; -; United Kingdom	Species: Canine Breed: Cockapoo Sex: M Sex qualifier: Unknown Age: - Weight: 15 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: FRONTLINE PETCARE HOME AND ENVIRONMENT FLEA SPRAY; Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	N/A	13-Aug-2019	1 Week(s)	D-D	As reported by the animal owner, a male Cockapoo dog, weighing 15 kg (signalment otherwise unknown), was treated with FRONTLINE SPOT ON DOG M (batch number: S21704BL, expiry date: OCT 2021), applied topically to the back of the neck, by the animal owner, once a month, with the last application 10 days ago (06 AUG 2019), for an unknown indication. The owner reported that when they treated the dog it didn't seem wet on the scruff of his neck. 1 week after product administration, the owner noticed fleas on him, went to a large pet retailer and a member of staff there said that she probably had an infestation in the house. The owner treated the house with FRONTLINE PETCARE HOMEGARD HOUSEHOLD FLEA SPRAY (batch number and expiry date unknown). The owner is seeing 5-6 fleas on the dog, and the owner lives in a rural area. All other pipettes in the pack have liquid in them. People in the home are also being bitten.
16-Aug-2019	UAE; 19UK002661;	Species: Canine Breed: French	6	1	0	Product used: FIPRONIL	N/A	Aug-2019*	N/A	D-C	As reported by the animal owner, Archie, a 4 year old, French Bulldog canine (signalment otherwise unknown), was treated with

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
 Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
 *indicates Approximate date or weight

Page 216 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00223

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	-, United Kingdom	Bulldog Sex: U Sex qualifier: Unknown Age: 4.00 Year(s) Weight: Unknown				10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company					FRONTLINE PLUS (estimated as FRONTLINE PLUS SPOT ON DOG M), batch number and expiry date unknown, applied topically to the back of the neck, by the animal owner, once a year, with the last application on an unknown date, as a preventative treatment. The owner reported that they have 6 dogs, all of which were treated with FRONTLINE PLUS. Archie specifically lost the fur on the back of his neck which is also bleeding/red raw. The owner has lived in their house for only 1 month, and has sprayed it with a home spray in a green tin. Start date of event added for submission purposes only. On 17 AUG 2019 the owner reported that they have had to rush Archie to the vets and have been told that his skin is badly burnt and infected and he's got to have tablets for the next 2 weeks and then go back to be seen to see if the infection has cleared up. The owner reported that it is very upsetting to watch their dog in pain and discomfort. Start date of event added for submission purposes only. Case linked to 19UK002662.
16-Aug-2019	UAE; 19UK002662; -, United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: 6.00 Year(s) Weight: Unknown	6	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, Nala, a 6 year old dog (signalment otherwise unknown), was treated with FRONTLINE PLUS (estimated as FRONTLINE PLUS SPOT ON DOG M), batch number and expiry date unknown, applied topically to the back of the neck, by the animal owner, with the last application on an unknown date, as a preventative treatment. The owner reported that they have 6 dogs, all of which were treated with FRONTLINE PLUS. A week after treating Nala, the owner saw a flea crawling on her. The owner has lived in their house for only 1 month, and has sprayed it with a home spray in a green tin. Start date of event added for submission purposes only. Case linked to 19UK002661.
16-Aug-2019	UAE; 19UK002663; Greater Manchester; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON; Route: unknown Was the product used ok?: Unknown to Company	15-Aug-2019	16-Aug-2019*	1 Day(s)	D-D	As reported by a veterinary nurse (also the animal owner), a dog (signalment otherwise unknown) was treated with FRONTLINE SPOT ON DOG (estimated as FRONTLINE SPOT ON DOG M) batch number and expiry date unknown, details unknown, by the animal owner, on 15 AUG 2019, for an unknown indication. The vet nurse reported that the dog is their only pet, and they normally use FRONTLINE COMBO (estimated as FRONTLINE COMBO SPOT ON DOG M) monthly, however her husband put FRONTLINE SPOT ON on the dog, on 15 AUG 2019. The vet nurse is seeing fleas and doesn't normally see them. The owner is not being bitten and does not spray the house.
16-Aug-2019	UAE; 19UK002664; -, United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the	N/A	06-Aug-2019	0 Day(s)	D-D	As reported by the animal owner, approximately 2 cats (signalment otherwise unknown), were treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), details unknown, by the animal owner, on 06 AUG 2019, for an unknown indication. The owner reported that they purchased the product from a large pet retailer. As soon as they got home they treated their cats straight away. Over a week has passed and the owner is less than pleased with the results. After combing their cats (which mostly stay in) the owner noticed that they still had fleas. One of the cats even reacted to the product (details of reaction unknown) which cost them even more money at the vet. Even the vet didn't

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 217 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00224

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						product used ok?: Unknown to Company					recommend the product.
16-Aug-2019	UAE; 19UK002668; -, United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a cat (signalment otherwise unknown), was treated with FRONTLINE SPOT ON CAT (batch number and expiry date unknown), details unknown, by the animal owner, on an unknown date, for an unknown indication. The owner reported that they always use FRONTLINE on their cat but it never works. The owner now has a flea infestation in their home because apparently, despite treating their cat frequently with the product as it advises, it does not work. Start date of event added for submission purposes only.
15-Aug-2019	UAE; 19UK002669; -, United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL SPOT ON CAT Other products used: FRONTLINE PETCARE HOME AND ENVIRONMENT FLEA SPRAY; Route: unknown Was the product used ok?: Unknown to Company	N/A	18-Jul-2019	N/A	D-D	As reported by the animal owner, 2 cats (signalment otherwise unknown), were treated with FRONTLINE (estimated as FRONTLINE SPOT ON CAT), batch number and expiry date unknown, details unknown, by the animal owner, twice, 2 weeks apart, for an unknown indication. The owner reported that the cats have had fleas for 4 weeks now. The owner reported it was their fault as they forgot their usual FRONTLINE treatment. The owner has treated them twice, 2 weeks apart, and has washed and is continuing to wash all bedding etc. including their own. They are hoovering constantly and spraying with FRONTLINE PETCARE HOMEGARD HOUSEHOLD FLEA SPRAY (batch number and expiry date unknown), but they are not winning this battle.
19-Aug-2019	UAE; 19UK002670; -, United Kingdom	Species: Canine Breed: Spaniel (Cocker) Sex: F Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a female, Cocker Spaniel dog (signalment otherwise unknown), was treated with FRONTLINE SPOT ON DOG (estimated as FRONTLINE SPOT ON DOG M), batch number: S21212AW, expiry date: AUG 2021, details unknown, by the animal owner, on an unknown date, for an unknown indication. The owner reported that the product is correct for the dog's weight range and that they have followed all the instructions for use. The dog was given 2 treatments over the prescribed period. She still has a lot of fleas, so the product is not working. The owner asked whether we have had a problem with this batch number. The owner has always used FRONTLINE products in the past on their dog and its been fantastic in treating flea infestations, but this one has been next to useless. Start date of event added for submission purposes only. UPDATE 26 SEP 2019: QA results were received. Investigation completed for FIPRONIL SPOT ON DOG Lot S21212AW, expiry 2021-08-31. Case investigated by France - Toulouse. Final complaint evaluation: A product quality complaint for FRONTLINE SPOT ON DOG M, batch number S21212AW, was received by BIAH QA on the 23 AUG 2019. The complaint description is lack of efficacy. This is the first complaint for this batch. The complaint sample is not received and pictures are not attached to this case. The retention sample is not reviewed because it is stored for identification purposes. Therefore, it is not applicable to this kind of defect. Batch records investigation: Batch record review: S212. Manufacturing date: 7/09/2018 - Expiry date: NA - Manufacturing

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 218 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

v1.2

ED_005739D_00014390-00225

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											quantity: 1199.4 liters. Associated deviation(s): No deviation associated to this batch. Change control associated: This batch was not concerned by any change control. Observation(s): No observation associated to this batch. Results of QC testing: Conform at specifications. All parameters verified during manufacturing of this bulk batch are conform. Batch record review: S21212.
16-Aug-2019	UAE; 19UK002673; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: Unspecified Home treatment; Route: unknown Was the product used ok?: Unknown to Company	N/A	16-Aug-2019	N/A	D-D	As reported by the animal owner, a cat (signalment otherwise unknown), was treated with FRONTLINE (estimated as FRONTLINE SPOT ON CAT) batch number and expiry date unknown, route and frequency unknown, administered by the cat's owner on an unspecified dates (the owner reported that they had used 6 batches however). The owner had also used an unspecified home treatment on numerous occasions. On 16 AUG 2019 the owner reported that the products were not working. No further information was supplied.
16-Aug-2019	UAE; 19UK002676; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	10	10	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	16-Aug-2019	2 Week(s)	D-D	As reported by the animal owner, 10 dogs (signalment otherwise unknown), were treated with FRONTLINE SPRAY (batch number: 502036A, expiry date unknown), details unknown, by the animals' owner, a fortnight ago (estimated as 02 AUG 2019), after seeing loads of fleas on the dogs. The owner reported that they got 15, 500 ml bottles of FRONTLINE SPRAY from an online retailer, and that they sprayed all their dogs with it and it hasn't killed the fleas. The owner saw loads of fleas, then sprayed the dogs and is now still seeing 5-6 fleas. The owner stated that the product hasn't worked. The owner has had dogs for 40 years.
17-Aug-2019	UAE; 19UK002678; -; United Kingdom	Species: Canine Breed: Yorkshire Terrier Sex: F Sex qualifier: Unknown Age: 14.00 Year(s) Weight: 2.5 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON; Route: unknown Was the product used ok?: Unknown to Company	N/A	17-Aug-2019	3 Day(s)	D-D	As reported by the animal owner, Bella, a 14 year old, female, Yorkshire Terrier dog, weighing 2.5 kg (signalment otherwise unknown), was treated with FRONTLINE SPOT ON DOG S (batch number and expiry date unknown), details unknown, by the animal owner, on 14 AUG 2019, for an unknown indication. The owner reported that 3 days after application the dog is running alive with fleas. The owner has used FRONTLINE PLUS SPOT ON DOG S in the past and had the same problem.
17-Aug-2019	UAE; 19UK002679; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: X Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the	15-Aug-2019*	17-Aug-2019	2 Day(s)	D-D	As reported by the animal owner, 1 male, and 1 female dog (signalment otherwise unknown), were treated with FRONTLINE PLUS SPOT ON DOG L (batch number and expiry date unknown), details unknown, by the animal owner, a couple of days ago (estimated as 15 AUG 2019), for an unknown indication. The owner reported that their 2 dogs had fleas. After speaking to a member of staff they were assured that, although FRONTLINE PLUS was the most expensive, it was the best product on the market. The owner used the correct treatment for the dog size (20-40 kg), however after a couple of days the fleas haven't died.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 219 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00226

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						product used ok?: Unknown to Company					The owner purchased a 3 shot pack and their female dog still has fleas after using 2 shots, and their male dog still has some fleas after using 1 pipette.
17-Aug-2019	UAE; 19UK002680; -; United Kingdom	Species: Canine Breed: Spaniel (Cocker) Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	15-Jul-2019*	17-Aug-2019	2 Day(s)	D-D	As reported by the animal owner, a male Cocker Spaniel dog (signalment otherwise unknown), was treated with FRONTLINE PLUS (estimated as FRONTLINE PLUS SPOT ON DOGS M) batch number and expiry date unknown, applied for the past 2 months, last applied by the owner on 15 AUG 2019 and the owner reported that the fleas were not going. The dog was bathed on 17 AUG 2019 (2 days after the last application) and dozens of fleas were washed out. That afternoon the owner used a flea comb and they removed another mass of them. The owner had hoovered daily and washed all the soft furnishings. The owner was running out of ideas. No further information was supplied.
17-Aug-2019	UAE; 19UK002681; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	17-Aug-2019	N/A	D-D	As reported by the animal owner, a dog (signalment otherwise unknown), was treated with FRONTLINE PLUS (estimated as FRONTLINE PLUS SPOT ON DOGS M) batch number and expiry date unknown, route and frequency unknown, administered by unknown, used for a while on both the dogs. The owner reported that they had found one of the dogs with fleas which showed that the chemicals were not working to the correct standard. The owner was not happy with the results as it was not working anymore. The owner had used the product on their 2 cats also (but had not reported a lack of effect for them). No further information was supplied.
18-Aug-2019	UAE; 19UK002684; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: F Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: FRONTLINE PETCARE HOME AND ENVIRONMENT FLEA SPRAY; Route: unknown Was the product used ok?: Unknown to Company	N/A	18-Aug-2019	8 Day(s)	D-D	As reported by the animal owner, a female dog (signalment otherwise unknown), was treated with FRONTLINE PLUS (estimated as FRONTLINE PLUS SPOT ON DOG M), batch number and expiry date unknown, details unknown, by the animal owner, 8 days ago (10 AUG 2019), for an unknown indication. The owner reported that 8 days after application they are still seeing live fleas. The owner has also treated their home with FRONTLINE PETCARE HOMEGARD HOUSEHOLD FLEA SPRAY (batch number and expiry date unknown). The owner is unsure whether the spot on they used was out of line (assumed meaning out of date) as they bought it online a couple of years ago in a bulk purchase, which would explain why the dog has got fleas in the first place.
18-Aug-2019	UAE; 19UK002685; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: F Sex qualifier: Unknown Age: -	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: FIPRONIL 10%/S METHOPRENE	N/A	Jul-2019*	0 Day(s)	D-D	As reported by the animal owner, a female cat (signalment otherwise unknown) was treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), details unknown, by the animal owner, on 16 AUG 2019, for an unknown indication. The owner reported that the product has not worked. The owner has spent all weekend bathing, defleaing and cleaning their house top to bottom. The owner reported that last months

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 220 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00227

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: Unknown				12% SPOT ON; Johnsons Veterinary Household Spray; Route: unknown Was the product used ok?: Unknown to Company					(estimated as JUL 2019) standard FRONTLINE (FRONTLINE SPOT ON CAT) didn't work, so they chose to use FRONTLINE PLUS and set up a subscription with a large pet retailer for monthly delivery. The owner has stressed their cat out to the max with trying to get her free from fleas and thought it was sorted. But the owner has just gone through her fur with a comb and she still has live fleas. The owner reported that they gave the cat 1 dose of treatment. The owner only has a receipt available as the packaging got thrown away. The owner has spent money on flea treatment for the cat, the house with 2 bottles of Johnsons Veterinary Household Spray, and brand new bedding for 2 beds in the house so they could treat everything and now they feel like they have wasted time and money. The owner treats the cat every month, mainly from spring to autumn, with the cat being able to go both indoors and outdoors, and the owner is seeing 15 fleas on the cat. The owner is being bitten and so is their daughter.
18-Aug-2019	UAE; 19UK002686; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: X Sex qualifier: Unknown Age: 15.00 Year(s) Weight: 2.7 - 4.5 kg*	3	3	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	May-2018*	04-Aug-2019*	N/A	D-D	As reported by the animal owner, Derek, a 15 year old, male cat, weighing approximately 4.5 kg (signalment otherwise unknown), Clive, a 15 year old, male cat, weighing approximately 4.5 kg (signalment otherwise unknown) and Georgia, a 16 year old, female cat, weighing approximately 2.7 kg (signalment otherwise unknown), were treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), applied topically to the back of the neck, by the animal owner, every 4 weeks, for 15-18 months, with the last applications on 05 JUN 2019, 03 JUL 2019, 03 AUG 2019, and 18 AUG 2019, for an unknown indication. The owner reported that they have now got a flea infestation. The last batch of pipettes they bought was from a large online retailer and the owner asked whether they were fake or if the fleas resistant to it. The owner first noticed fleas on their pets 2 weeks ago, people in the home are not being bitten by the fleas, the cats spend time both indoors and outdoors, and all animals in the house including all in contact animals have been treated with a flea product. The owner reported that they are seeing more than 5 fleas on their pets at a time, the cats never go swimming and are never bathed, they have lived in their house for over 1 year, and they have regularly vacuumed all areas of the home that the pets can access. The owner has not treated the home with an environmental flea spray and has not washed their pets bedding at over 60 degrees Celsius. UPDATE 24 SEP 2019: QA results received. Investigation completed for FIPRONIL 10%/S METHOPRENE 12% SPOT ON Lot Unknown, expiry. Case investigated by France - Toulouse. Final complaint evaluation: An adverse event for FRONTLINE PLUS SPOT ON CATS, batch unknown, was received by BIAH QA on the 27th of August 2019. This is the 27th complaint received for LOE, in the past 12 months, all batches of Frontline Cats. This defect is rare, it represents 0.2 ppm of every batch produced in 2017 (17 complaints for 78 447 597
19-Aug-2019	UAE; 19UK002687; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: Acclaim;	N/A	2019*	N/A	D-D	As reported by the animal owner, 1 dog (signalment otherwise unknown) was treated with FRONTLINE PLUS SPOT ON (estimated as FRONTLINE PLUS SPOT ON DOG M), batch number and expiry date unknown, details unknown, by the animal owner, on an unknown date, for an unknown indication. The owner reported that they think they might have bought a fake FRONTLINE PLUS SPOT ON. The owner has sprayed the whole house with Acclaim and they use this spray for their rental properties, but the spot on they've put on the dog doesn't seem to

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 221 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00228

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Route: unknown Was the product used ok?: Unknown to Company					be working. The owner asked for help for the itching and biting. The website the owner checked it out on said that if its a fake as the packets in the cardboard container are not separated and the cover is quite plain in the pipette cover, yet theirs is plastered with FRONTLINE PLUS stripes etc. Prior to this FRONTLINE has always worked. Start date of event added for submission purposes only.
19-Aug-2019	UAE; 19UK002692; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: F Sex qualifier: Neutered Age: 4.25 Month(s) Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	20-Jun-2019	Aug-2019*	N/A	D-D	As reported by the animal owner, Nicky, a 4 month 1 week old, neutered, female kitten, breed unknown, of unknown weight, and of good health was treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), correctly applied topically to the back of the neck, by the animal owner, monthly, from 20 JUN 2019 to 19 AUG 2019, to start the kitten's flea treatment. The owner reported that they bought the FRONTLINE PLUS from their local pharmacy and the kitten still has fleas. Quite a few fleas are still being seen and the owner's partner is being bitten. They live in a new build house and the kitten hasn't been outside. The owner no longer wishes to use FRONTLINE PLUS moving forward and has purchased another product. Start date of event added for submission purposes only.
19-Aug-2019	UAE; 19UK002695; -; United Kingdom	Species: Canine Breed: Shih Tzu Sex: F Sex qualifier: Neutered Age: 3.00 Year(s) Weight: 6 - 8 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: Prinovox; Route: Topical / Cutaneous Was the product used ok?: Yes	09-Aug-2019	10-Aug-2019	1 Day(s)	D-D	As reported by the animal owner, Rosie, a 3 year old, neutered, female, Shih Tzu dog, weighing between 6 and 8 kg, and of good health was treated with FRONTLINE PLUS SPOT ON DOG S (batch number: S60328BL, expiry date: JAN 2021), correctly applied topically to the back of the neck, by the animal owner, on 09 AUG 2019, for an unknown indication. The owner reported that they purchased FRONTLINE PLUS from the chemist on 09 AUG 2019 and applied it that day, and then dropped the dog off at the dog sitter. The owner picked up the dog that Saturday (10 AUG 2019) and the dog was scratching a lot. The owner could see live bugs in her coat and that evening bathed her to try and get all the fleas off her, but they obviously missed some as they could still see them, about 10 or more. The dog has scratched herself so much she has caused red marks on her skin. The owner is going to the vets on Wednesday for it to be checked. Before using the FRONTLINE, the owner was using Prinovox flea treatment from the vets, which has always worked and they have never had flea problems until using the FRONTLINE PLUS. The owner is very unhappy as they have paid lots of money and the product doesn't work. No one in the house is being bitten and the dog sitter didn't mention to the owner that she was being bitten. The owner's daughter is ill and is having chemo so if a flea bites her and she gets an infection, they will be seriously angry. The owner has sprayed the house with a spray from the vets and has vacuumed everywhere, emptying the vacuum each time.
19-Aug-2019	UAE; 19UK002696; -; United Kingdom	Species: Canine Breed: Canine various breeds Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the	N/A	14-Aug-2019	1 Week(s)	D-D	As reported by the animal owner, a small Jack Russel dog (signalment otherwise unknown), and Mitzi a 2 year old female small Poodle cross dog weighing 5 kg (signalment otherwise unknown) were treated with FRONTLINE PLUS SPOT ON DOG S (batch number S62713AW and expiry date SEP 2021), topically to the back of the neck after parting the hair, by the animal owner, on 07 AUG 2019, for fleas. The owner reported that they didn't see any fleas for a week but now they have fleas again. The animal owner adds that they treat the animals when they see fleas and only over the summer. The animal owner first noticed fleas on their pet on 05 AUG 2019 and no one in the home is being bitten. The

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 222 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00229

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						product used ok?: Unknown to Company					animals spend time indoors and outdoors and all animals that live in the household and in contact animals have been treated with a flea product. The animal owner adds that they are seeing occasional fleas - less than 5 at the same time, the animals are bathed or go swimming once every 6 weeks and they have treated the home with an environmental flea spray, washed the pet's bedding at over 60 degrees and regularly vacuumed all areas that the pets can access.
19-Aug-2019	UAE; 19UK002697; -, United Kingdom	Species: Canine Breed: West Highland White Sex: F Sex qualifier: Neutered Age: 6.00 Year(s) Weight: 10 kg*	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	May-2019*	18-Aug-2019	N/A	D-D	As reported by the animal owner, Sky, a 6 year old, neutered, female West Highland Terrier dog, weighing around 10 kg and of good health, and Lola, a 6 year old, neutered, female West Highland Terrier dog, weighing around 10 kg and of good health were treated with FRONTLINE PLUS SPOT ON DOG S (batch number: S61716AL, expiry date: JUN 2021), correctly applied topically to the back of the neck, by the animal owner, for 3 months, every 4 weeks, as a parasiticide after seeing ticks on the dogs. The owner reported that they are still seeing ticks on the dogs. The owner lives in an area where there are a lot of ticks. The owner saw 4 live ticks on her dog on 18 AUG 2019. Both dogs are being treated every 4 weeks. The owner mentioned that the dogs have put on a bit of weight so may be over 10 kg now.
19-Aug-2019	UAE; 19UK002700; County Durham; United Kingdom	Species: Feline Breed: Feline Other Sex: F Sex qualifier: - Age: 16.00 Week(s) Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	N/A	16-Aug-2019*	0 Day(s)	D-D	As reported by the animal owner, Pebbles a female, intact, 16 week old kitten (a domestic cat) was treated with FRONTLINE PLUS SPOT ON CAT (batch number: S4141303AW and expiry date: OCT 2021), applied topically by the cat's owner every 30 days, last applied on 16 AUG 2019 and since the product was administered the owner reported that they are seeing 3 fleas a day and the owner had been bitten.
19-Aug-2019	UAE; 19UK002702; -, United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, 2 dogs (signalment otherwise unknown), were treated with FRONTLINE SPRAY (batch number: R01107A, expiry date: FEB 2020), details unknown, by the animal owner, on an unknown date, for an unknown indication. The owner reported that they have found the FRONTLINE SPRAY to be completely ineffective. The owner understands the life cycle of fleas and how a heavily infested house can mean treatment of the pet is not sufficient to control an infestation but they are a pest controller and their house is not infested. The pets are treated regularly with veterinary flea and worm product. The owner queried if it was a duff batch. Start date of event added for submission purposes only. UPDATE 27 SEP 2019: QA results received. Investigation completed for FIPRONIL SPRAY Lot R01107A, expiry 2020-02-28. Case investigated by France - Toulouse. Final complaint evaluation: A product quality complaint for FRONTLINE Spray batch R01107A was received by BIAH QA on 28th August 2019. The complaint description is lack efficacy. This is the first complaint regarding this defect for this batch. The retention sample is conform (aspect) The sample complaint is not received and not requested. Batch

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
 Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
 *indicates Approximate date or weight

Page 223 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00230

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											record investigation Bulk batch: R011. Manufacturing date: 06/03/2017 - Expiry date: 02/2020 - Manufacturing quantity: 8497 liters. No deviation and observation are associated to this batch. This batch was not concerned by any change control. The results of QC testing are conform at specifications. All parameters verified during manufacturing of this batch of bulk are conform Filling batch: R41107A. Manufacturing date: 09/03/2017 - Expiry date: 02/2020 - Manufacturing quantity: 1596 bottles. No deviation and observation are associated to this batch. This batch was not concerned by any change control. For the filling batch, no IPC required concerning this kind of defect. Root cause : not established on Toulouse plant Description:After verification of batch records
19-Aug-2019	UAE; 19UK002703; Surrey; United Kingdom	Species: Canine Breed: Retriever Labrador Sex: U Sex qualifier: Unknown Age: 4.00 Year(s) Weight: Unknown	4	4	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	May-2019*	Aug-2019*	N/A	D-D	As reported by the animal owner, their 4 Labradoodle dogs: Nala, Ebony, Dizzy and Jack aged between 4 and 11 years (signalment otherwise unknown) were treated with FRONTLINE PLUS SPOT ON DOGS XL (batch number and expiry date unknown), applied correctly to the dogs, by the owner for the last few months. The owner reported on 19 AUG 2019 that they were struggling to get on top of the flea infestation. The owner reported that the dogs went to the groomers 48 hours after the application. Case linked to 19UK002705.
19-Aug-2019	UAE; 19UK002704; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	27 Day(s)	D-D	As reported by the animal owner, a dog (signalment otherwise unknown) was treated with FRONTLINE (estimated as FRONTLINE SPOT ON DOG M) batch number and expiry date unknown, details unknown, by the animal owner, on the 1st of the month, every month, for many years now, for an unknown indication. The owner reported that they have never had an issue before, yet for some reason unknown to them their dog has fleas this year. The owner confirmed on 20 AUG 2019 that their dog still caught fleas despite using the product.
19-Aug-2019	UAE; 19UK002705; Surrey; United Kingdom	Species: Canine Breed: Canine various breeds Sex: U Sex qualifier: Unknown Age: 4.00 Year(s) Weight: Unknown	4	4	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	N/A	19-Aug-2019	N/A	D-D	As reported by the animal owner, two toy poodle dogs Bertie and Twinkle and two miniature schnauzer dogs, Rosie and Precious aged between 4 and 11 years (signalment otherwise unknown) were treated with FRONTLINE PLUS SPOT ON DOGS S (batch number and expiry date unknown), applied correctly to the dogs, by the owner for the last few months. The owner reported on 19 AUG 2019 that they were struggling to get on top of the flea infestation. The owner reported that the dogs went to the groomers 48 hours after the application. Case linked to 19UK002703.
19-Aug-2019	UAE; 19UK002706; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products	N/A	2019*	N/A	D-D	As reported by the animal owner, a dog (signalment otherwise unknown) was treated with FRONTLINE SPOT ON (estimated as FRONTLINE SPOT ON DOG M) batch number and expiry date unknown, details unknown, by the animal owner, on an unknown

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 224 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00231

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: Unknown Age: - Weight: Unknown				used: FRONTLINE PETCARE HOME AND ENVIRONMENT FLEA SPRAY; Route: unknown Was the product used ok?: Unknown to Company					date, for an unknown indication. The owner reported that they have been using FRONTLINE SPOT ON and FRONTLINE PETCARE HOMEGARD HOUSEHOLD FLEA SPRAY (batch number and expiry date unknown) used as an additional treatment for the carpet, but there are fleas still on their dog and cat. The owner has been grooming every day, and started bathing their dog after a week on FRONTLINE as it did not seem to be working, and have bathed it everyday since. The owner has a second batch of FRONTLINE coming from a large pet retailer. The have now spoken to the vet who has recommended a prescription tablet for both the dog and the cat. Start date of event added for submission purposes only. Case linked to 19UK002707.
19-Aug-2019	UAE; 19UK002707; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: FRONTLINE PETCARE HOME AND ENVIRONMENT FLEA SPRAY; Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a cat (signalment otherwise unknown) was treated with FRONTLINE SPOT ON CAT (batch number and expiry date unknown) details unknown, by the animal owner, on an unknown date, for an unknown indication. The owner reported that they have been using FRONTLINE SPOT ON and FRONTLINE PETCARE HOMEGARD HOUSEHOLD FLEA SPRAY (batch number and expiry date unknown), used as an additional treatment for the carpet, but there are fleas still on their dog and cat. The owner has been grooming every day, and started bathing their dog after a week on FRONTLINE as it did not seem to be working, and have bathed it everyday since. The owner has a second batch of FRONTLINE coming from a large pet retailer. The have now spoken to the vet who has recommended a prescription tablet for both the dog and the cat. Start date of event added for submission purposes only. Case linked to 19UK002706.
19-Aug-2019	UAE; 19UK002713; Greater London; United Kingdom	Species: Canine Breed: Yorkshire Terrier Sex: U Sex qualifier: Unknown Age: 5.00 Year(s) Weight: 5.2 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: AFOXOLANER 18.75 MG / MILBEMYCIN OXIME 3.75 MG CHEWABLE TABLETS; Advocate; Indorex; Unspecified herbal flea collar; Route: unknown Was the product used ok?: Unknown to Company	Jun-2019*	Jun-2019*	0 Day(s)	D-D	As reported by a member of the vet clinic staff, Dolly, a 5 year old, Yorkshire Terrier dog, weighing 5.2 kg (signalment otherwise unknown), was treated with NEXGARD SPECTRA S (batch number and expiry date unknown) administered orally, by the animal owner, on 02 AUG 2019, as a parasiticide after seeing fleas. The animal owner is still seeing fleas. The member of vet clinic staff reported that previous to this dose of NEXGARD SPECTRA, the owner had given the dog 2 doses of Advocate, with the first in the first week of JUL 2019, again because they were seeing fleas, but nothing was given prior to this. The owner reported that at the beginning of JUN 2019 they went on holiday and boarded Dolly, and when they picked her up she was scratching and itching a lot. The owner treated the dog with a flea shampoo, but this didn't work, so they waited another week and did another flea shampoo, which also didn't work. The owner got some FRONTLINE (assumed FRONTLINE SPOT ON DOG S, batch number and expiry date unknown), which didn't work. In the first week of July the owner applied Advocate, which also didn't work. The owner then got a herbal flea collar as they don't like giving the dog too many chemicals, but this didn't work either and the owner saw fleas on the collar. On AUG 02 2019 the animal was taken to the vet, who saw fleas on her, and gave NEXGARD SPECTRA. The owner has used Indorex Spray and vacuumed. No one in the house is being bitten. Before June the owner had never used a flea product because they had never had a problem.
20-Aug-2019	UAE; 19UK002717; -; United Kingdom	Species: Canine Breed: Border Collie	3	3	0	Product used: FIPRONIL 10%/S	17-Aug-2019	Aug-2019*	N/A	D-D	As reported by the animal owner, Nell, a 6 year old, neutered, female, Boarder Collie dog, weighing 18 kg, and of good health, Poppy, a 9 year old, neutered, female, Boarder Collie Dog,

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 225 of 867

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00232

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex: F Sex qualifier: Neutered Age: 6.00 Year(s) Weight: 18 - 20 kg				METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes					weighing 19 kg, and of good health, and Ness, a 10 year old, neutered, female, Boarder Collie dog, weighing 20 kg, and of good health were treated with FRONTLINE PLUS SPOT ON DOG M (batch number: 963017AL, expiry date: 30 SEP 2021), correctly administered topically to the back of the neck, by the animal owner, on 17 AUG 2019, after seeing fleas. The owner reported that this was the first time they had used FRONTLINE PLUS on their dogs. 5-6 fleas are being seen in total across the 3 dogs. The owner is not being bitten and no fleas can be seen within the home. 1 of the dogs is irritated and a bit sore, and may have flea allergy dermatitis.
20-Aug-2019	UAE; 19UK002719; -, United Kingdom	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: M Sex qualifier: Neutered Age: - Weight: 5.7 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: RIP flea spray; Route: Topical / Cutaneous Was the product used ok?: Yes	Dec-2018*	Apr-2019	N/A	D-D	As reported by the animal owner, Blackie, a neutered, male Domestic Shorthair cat, age unknown, weighing 5.7 kg, and of good health was treated with FRONTLINE PLUS SPOT ON CAT (batch numbers: R40718AW, S40203AW, expiry dates: JUN 2020, DEC 2020) correctly administered topically to the back of the neck, by the animal owner, every month, for 8 months, for an unknown indication. The owner reported that she has a flea infestation. The owner moved in a year ago but to a completely empty, brand new house, with no pre-existing infestation. The cat is having a terrible skin disaster due to the flea bites, he licked himself raw and so the owner took him to the vet in APR 2019. The vet said to give the cat Staykill but the owner refused to over medicate, and the vet gave him an injection to relax the itching (product unknown). There is lots of flea dirt on the cat. The owner's mother told her 50 years ago to hold the cat's tail and go through the fur and put alcohol on each flea and make it go numb. The owner is being bitten by the fleas and the fleas jump onto her naked legs. The owner reported that there are different fleas in the cat's coat (shiny rings) but the fleas that jump on her legs are black and no bigger than a black full stop on paper. They are confining the cat to one room. The owner has been spraying every week with RIP flea and covered the floor in white sheets, hoovering every second day, and has also washed the bedding at 60 degrees or above. The cat does not wear a collar
20-Aug-2019	UAE; 19UK002720; -, United Kingdom	Species: Canine Breed: Terrier (Jack Russell) Sex: M Sex qualifier: Neutered Age: 7.00 Year(s) Weight: 7 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	Aug-2019*	9 Day(s)	D-D	As reported by the animal owner, Shipley, a 7 year old, neutered, male Jack Russell Terrier dog, weighing 7 kg and of good health was treated with FRONTLINE (estimated as FRONTLINE SPOT ON DOG S) details unknown, by the animal owner, every 12 weeks, with the last application on 12 AUG 2019, for an unknown indication. The owner reported that they shampooed the dog on the 13 AUG 2019 and have been spraying the house all weekend. The owner is not being bitten but the dog has fleas.
20-Aug-2019	UAE; 19UK002721; Staffordshire; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used	N/A	21-Aug-2019	N/A	D-D	As reported by the animal owner, their 2 dogs (signalment otherwise unknown) were treated with FRONTLINE SPOT ON DOG S (batch number: R2113A and expiry date: MAY 2020), 1 pipette for each dog, administered by the owner as per instructions, on 01 AUG 2019 in order to rid the dogs of fleas. On 21 AUG 2019 the owner reported that the dogs were not flea free. No further information was supplied. UPDATE 27 SEP 2019: QA results received. Investigation completed for FIPRONIL SPOT ON DOG Lot R21113A, expiry 2020-05-31. Case investigated by France - Toulouse. Final

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 226 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00233

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						ok?: Yes					complaint evaluation: A product quality complaint for FRONTLINE SPOT ON DOG, batch R21113A, was received by BIAH QA on 30th August 2019. The complaint description is lack of efficacy . This is the first complaint regarding this defect for this batch. The retention sample is conform (aspect). The sample complaint is not received and requested. No pictures are attached for this case. Batch record investigation B. Bulk batch: R211. Manufacturing date: 21/06/17 - Expiry date: 05/2020 - Manufacturing quantity: 1199 liters. One deviation and two observations was not associated to this defect. This batch was not concerned by any change control. The results of QC testing are conform at specifications. All parameters verified during manufacturing of this batch of bulk are conform. Filling batch: R21113. Manufacturing date: 21/08/17 - Expiry date: 05/2020 - Manufacturing quantity: 21 000 blisters. No deviation is associated to this batch and two observations was not associated to this defect. This batch was not concerned by any change control. The results of QC testing are conform at specifications. During the filling, the volume is controlled every 30 minutes. 60 pipettes were conform. Root cause: No root cause could be identified on Toulouse plant . Description: After verification of batch records and certificate of analysis, no relation can be established between this related adverse event and the manufacturing process
20-Aug-2019	UAE; 19UK002722; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, approximately 2 cats (signalment otherwise unknown) were treated with FRONTLINE (assumed FRONTLINE SPOT ON CAT batch number and expiry date unknown, product unsubstantiated) details unknown, by the animal owner, on an unknown date, for an unknown indication. The owner reported that they bought FRONTLINE for their cats from their local pharmacy and it hasn't worked. Start date of event added for submission purposes only.
20-Aug-2019	UAE; 19UK002725; -; United Kingdom	Species: Canine Breed: Spaniel (Cocker) Sex: M Sex qualifier: Unknown Age: 7.00 Month(s) Weight: 10 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: No (Overdose)	15-Aug-2019	18-Aug-2019	N/A	D-D	As reported by the animal owner, a Cocker Spaniel puppy aged 7 months and weighing 10 kg (signalment otherwise unknown), was given FRONTLINE PLUS SPOT ON DOG S (batch and expiry unknown) on 15 AUG 2019 at a dose of one dosage form by the animal owner as a parasiticide. The animal owner reports that they cannot get rid of the fleas on the puppy. Three days after the first administration (on 18 AUG 2019), there were still fleas alive on the dog so the animal owner administered another half a pipette. The dog did get slightly damp within 48 hours of the first administration as there was a slight shower, but they did stop the dog from swimming. The dog has both adult fleas which are red and baby ones which are black. The animal owner has also washed the dog's bed, blanket and anything else he has been in contact with, and have hoovered thoroughly.
20-Aug-2019	UAE; 19UK002726; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: F Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous	N/A	20-Aug-2019*	N/A	D-D	As reported by the animal owner, a female feline (signalment otherwise unknown) was given FRONTLINE SPOT ON CAT (batch and expiry unknown) topically by the animal owner on approximately 15 AUG 2019 for parasite control. The animal owner reports that they applied it to the skin behind the neck on the cat and it has not worked. A few fleas had died off but still many remain. The cat only had a minor flea problem as she is usually treated monthly with other flea treatment (product unknown). The

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 227 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00234

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Was the product used ok?: Unknown to Company					house is treated regularly (product unknown).
20-Aug-2019	UAE; 19UK002727; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: M Sex qualifier: Unknown Age: 17.00 Year(s) Weight: 4.000 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	2017*	20-Aug-2019	4 Day(s)	D-D	As reported by the animal owner, a 17 year old, male cat, weighing 4 kg (signalment otherwise unknown) was treated with FRONTLINE PLUS SPOT ON CAT (batch number: S41303AW, expiry date: OCT 2021), applied topically to the back of the neck, by the animal owner, every month for a couple of years (estimated as 2017), with the last applications on 16 MAY 2019, 16 JUN 2019, 16 JUL 2019, and 16 AUG 2019, used as a parasiticide. The owner reported that they have always used FRONTLINE SPOT ON CAT (batch number and expiry date unknown) and are now using FRONTLINE PLUS for a couple of years now. The owner fleas the cat all the time but he has fleas now. They noticed the fleas on 15 AUG 2019 so they put another pipette on the cat as it was only a couple of days off 4 weeks since last administration. The cat however still has jumping fleas and eggs after 4 days. The owner uses the product all year round for the last 10 years. There are no human bites in the house and the owner has treated the house top to bottom (product unknown). When they flea comb the cat the notice loads of black bits (poo) and then 3 or 4 fleas but he won't let you comb him for long as he scratches the owner. The cat has no collar and they have lived in their house for over 16 years.
20-Aug-2019	UAE; 19UK002729; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: F Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: FRONTLINE PETCARE HOME AND ENVIRONMENT FLEA SPRAY; Route: unknown Was the product used ok?: Unknown to Company	N/A	2019	N/A	D-D	As reported by the animal owner, a female cat (signalment otherwise unknown) was treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown) by the animal owner and attending veterinary surgeon, over the past 4-5 months, for an unknown indication. The owner reported that they have used FRONTLINE PLUS on their cat and FRONTLINE PETCARE HOMEGARD HOUSEHOLD FLEA SPRAY (batch number and expiry date unknown) for the whole house and furniture and nothing seems to be working. The owner has got every nook and cranny in the house and has hoovered everywhere, every day, and still keeps finding fleas. The owner has had the cat flead at the vets also and had her taken away from the house for 48 hours while they fumigated the house. The owner has used other products like bombs and they comb the cat every day and still find fleas. Start date of event added for submission purposes only.
20-Aug-2019	UAE; 19UK002730; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	14-Aug-2019*	0 Day(s)	D-D	As reported by the animal owner, approximately 2 dogs (signalment otherwise unknown) were treated with FRONTLINE PLUS (estimated as FRONTLINE PLUS SPOT ON DOG M) batch number and expiry date unknown, details unknown, by the animal owner, less than a week ago (estimated as 14 AUG 2019), for an unknown indication. The owner reported that they also purchased some FRONTLINE PLUS for dogs and some for their cats like they usually do and they have got fleas. Case linked to 19UK002731.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 228 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00235

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
20-Aug-2019	UAE; 19UK002731; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	14-Aug-2019	0 Day(s)	D-D	As reported by the animal owner, approximately 2 cats (signalment otherwise unknown) were treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), details unknown, by the animal owner, less than a week ago (estimated as 14 AUG 2019), for an unknown indication. The owner reported that they also purchased some FRONTLINE PLUS for dogs and some for their cats like they usually do and they have got fleas. Case linked to 19UK002730.
21-Aug-2019	UAE; 19UK002736; Merseyside; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by a member of the veterinary clinic staff, a dog (signalment otherwise unknown) was treated with over the counter FRONTLINE (estimated as FRONTLINE SPOT ON DOG M), batch number and expiry date unknown, details unknown, by the animal owner, on an unknown date, for an unknown indication. The member of vet clinic staff reported that they have had a client into their vet practice who requested them to e-mail regarding the over the counter flea/tick FRONTLINE. The client had noticed that his dog still has quite a few ticks attaching for a period of time after using the product. The member of vet clinic staff did speak to the client regarding different medications/FRONTLINE COMBO but the client requested to send the e-mail as an adverse reaction report. Start date of event added for submission purposes only.
21-Aug-2019	UAE; 19UK002737; -; United Kingdom	Species: Canine Breed: Retriever (Labrador, Chocolate) Sex: F Sex qualifier: Unknown Age: 3.00 Year(s) Weight: 30 kg*	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: Indorex; Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	11-Jun-2019	Jun-2019	N/A	D-D	As reported by the animal owner, Tia, a 3 year old, female Chocolate Labrador dog, weighing between 29 and 30 kg (signalment otherwise unknown) was treated with FRONTLINE PLUS SPOT ON DOG L (batch number: S60205AR, expiry date: JAN 2021), applied topically between the shoulder blades, by the animal owner, monthly, on 11 JUN 2019, 15 JUL 2019, and 12 AUG 2019, for an unknown indication. The owner reported that they recently decided to change from their usual flea treatment to using FRONTLINE PLUS SPOT ON DOG L. The owner purchased a 3 pack on 02 MAY 2019, it is now 21 AUG 2019 and they have just had to take their dog to the vets for prescription flea treatment that has resulted in a vets bill and their dog being in extreme discomfort and distress for the past month and a half, after noticing fleas on the dog in JUN 2019, as the product has failed to work. The owner has also had to purchase Indorex. This is the first time the dog has had fleas due to the inadequate product. The owner reported that they use a flea product on their dog all year round, people in the house are not being bitten by the fleas, the dog spends time both indoors and outdoors, and they are seeing occasional fleas on their dog, less than 5 at a time. The dog isn't bathed and does not go swimming more than once a week, and this does not occur within 2 days of product administration. The owner has lived in their house for more than a year, and has washed their pets bedding at over 60 degrees Celsius and regularly vacuums all areas the pets can access. The animal owner added that the animal is 3 years old and they have never had any problems with fleas during this time while using Advantage products. Alongside Advantage pet treatments, the animal owner reported that their home is regularly treated with Indorex Defence Spray.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 229 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00236

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
21-Aug-2019	UAE; 19UK002738; -; United Kingdom	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: X Sex qualifier: Unknown Age: 2.00 Year(s) Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: FIPRONIL SPOT ON CAT; Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	17-Aug-2019	31-Jul-2019	N/A	D-D	As reported by the animal owner, Link, a 2 year old, male, medium/average sized (exact weight unknown), Domestic Shorthair cat (signalment otherwise unknown), and Loki, a 2 year old, female, medium/average sized (exact weight unknown), Domestic Shorthair cat (signalment otherwise unknown) were treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), applied topically to the back of the neck, by the animal owner, on 17 AUG 2019, for an unknown indication. The owner reported that they used to use FRONTLINE SPOT ON CAT (batch number and expiry date unknown), every month, all year round, specifically on 1 JUN 2019, 01 JUL 2019, and 31 JUL 2019, but the cats still got fleas and brought them into the house which was first noticed by the owner on 31 JUL 2019. They then tried FRONTLINE PLUS, however on 21 AUG 2019 the owner reported that the cats are still scratching. They can't see any fleas on the cats but there is definitely flea 'poo' in their fur and its falling off them when they walk around. On the night of 21 AUG 2019 the owner reported that they found at least 3 very alive fleas on Link's fur, but the other cat is a scaredy cat so it will be hard to check her. The owner asked if it has possibly not worked. The owner has sprayed (product unknown) and hoovered the house constantly and they keep being bitten themselves so they are desperate to get on top of this. The owner reported that all adults and children in the house are being bitten to death and are miserable. The cats spend time indoors and outdoors, all animals in the household and all in contact animals have been treated with a flea product, the cats are never bathed and never go swimming, and the owner has lived in their house for more than 1 year. The owner has hoovered all areas the pets can access, has washed and sprayed the house multiple times, had Rentokill out, and has washed their cat's bedding at over 60 degrees Celsius. The cats are fully grown now.
21-Aug-2019	UAE; 19UK002739; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	21-Aug-2019	2 Week(s)	D-D	As reported by the animal owner, approximately 2 cats (signalment otherwise unknown) were treated with FRONTLINE SPOT ON CAT (batch number and expiry date unknown), details unknown, by the animal owner, 2 weeks ago (estimated as 07 AUG 2019), for an unknown indication. The owner reported that 2 weeks after administration they were all infested with fleas which they didn't have before. The owner is completely unsatisfied with this product and coming from a veterinary professional it is virtually a waste of money buying.
21-Aug-2019	UAE; 19UK002740; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: 13.00 Year(s) Weight: 3.3 - 4.8 kg	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	N/A	21-Aug-2019	0 Day(s)	D-D	As reported by the animal owner, a 17 year old cat, weighing 3.3 kg, and a 13 year old cat, weighing 4.8 kg (signalment otherwise unknown) were treated with FRONTLINE PLUS SPOT ON CAT (batch number: S41113AW, expiry date: AUG 2021), applied topically, by the animal owner, for the past few months, with the last dose dates on 30 JUL 2019 (approximately), and 21 AUG 2019, as a parasiticide. The owner reported that they purchased the product through an online retailer and included 12 months flea and worm treatment. They reported that the product didn't eliminate any fleas, despite the fact it has been used for the past few months, furthermore, the flea issue is still ongoing. The treatment was administered as advised on the package and the whole property was cleaned with additional products to eliminate the fleas at home, including an environmental flea spray used

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 230 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00237

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											since the flea issue began, and on a weekly basis since. The owner has lived in the property for over a year and has also regularly vacuumed all areas the pets can access, and washed all of the pets bedding, which has also been dry cleaned. The owner reported that the issue remains. On 23 AUG 2019, the owner reported that they use a flea product on their pets all year round, they first noticed the fleas a month and a half ago, and the FRONTLINE PLUS was applied as soon as they received the product. People in the house are being bitten by the fleas, the fleas are not visible but there is constant scratching witnessed of the cats, and fleas are jumping onto humans. The owner reported that there is clear evidence of fleas. The cats don't wear collars and have not been bathed since the product was applied.
21-Aug-2019	UAE; 19UK002743; -; United Kingdom	Species: Feline Breed: Ragdoll Sex: F Sex qualifier: Neutered Age: 6.00 Year(s) Weight: 9 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: Drontal Spot on Wormer; Route: Topical / Cutaneous Was the product used ok?: Yes	N/A	20-Aug-2019	0 Day(s)	D-D	As reported by the animal owner, Madison, a 6 year old female neutered Ragdoll feline, weighing 9 pounds (4.1 kg) and in good condition, was treated with FRONTLINE PLUS SPOT ON CAT (batch number T40208A and expiry date JAN 2022), applied topically to an unknown site, by the animal owner, on 20 AUG 2019, for an unknown indication. The owner reported that they had just applied the FRONTLINE PLUS onto their cat, she has them every month and is ok with them but this time it has left her fur around the treated area dark grey/ almost black. The cat seems fine but this has never happened before. The animal owner reported that the colour change happened straight away after applying the product, but has a theory. The animal owner stated that a few days before, they had put a Drontal Spot on Wormer in the same place and so wonders if it may have been an interaction between the two products being on the coat. The animal was not poorly and was not bothered by it at all. No treatment was needed and after 3 to 4 days the coat was normal again. The animal owner wanted to stress that it was not a complaint, they think that the products are marvelous and is on a subscription scheme.
21-Aug-2019	UAE; 19UK002744; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	16-Aug-2019*	N/A	D-D	As reported by the animal owner, a dog (signalment otherwise unknown) was treated with FRONTLINE (estimated as FRONTLINE SPOT ON DOG M), batch number and expiry date unknown, details unknown, by the animal owner, about 5 days ago (estimated as 16 AUG 2019), for an unknown indication. The owner reported that they have still seen live fleas on their pet.
19-Aug-2019	UAE; 19UK002745; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a male dog (signalment otherwise unknown) was treated with FRONTLINE PLUS SPOT ON DOG (estimated as FRONTLINE PLUS SPOT ON DOG M), batch number: R61401AL, expiry date: JUN 2020, details unknown, by the animal owner, on an unknown date, for an unknown indication. The owner reported that they purchased the FRONTLINE PLUS from their local chemists and it was completely useless. The owner also reported that the whole house has been sprayed with a flea control substance, the carpets have been shampooed and the dog's bedding laundered. Start date of event added for submission purposes only.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 231 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00238

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
22-Aug-2019	UAE; 19UK002748; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	Aug-2019*	N/A	D-D	As reported by the animal owner, a dog (signalment otherwise unknown) was treated with FRONTLINE SPOT ON DOG (estimated as FRONTLINE SPOT ON DOG M), batch number and expiry date unknown, details unknown, by the animal owner, for an unknown indication. The owner reported that the product has not done what we state it will, kill fleas, ticks or lice. The owner applied it as the instructions stated. The dog still has fleas and the owner hoovers every day, so they cannot see why the treatment is not working. Start date for submission purposes only.
22-Aug-2019	UAE; 19UK002751; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: Indorex; Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	17-Aug-2019	17-Aug-2019*	N/A	D-D	As reported by the animal owner, approximately 2 cats (signalment otherwise unknown) were treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), applied topically to the back of the neck, by the animal owner, on 17 AUG 2019, for an unknown indication. The owner reported that at the same time as the FRONTLINE treatment, the house was washed, hoovered, sprayed with flea treatment (Indorex), and they used the foggers. All the owner's cats have still got live fleas on them and they can't use any more treatment as it will overdose them. The owner reported that they put the treatment on correctly on the skin of the neck. The owner is not happy that the treatment has not worked.
22-Aug-2019	UAE; 19UK002756; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: F Sex qualifier: - Age: 12.00 Month(s) Weight: 11 - 15 kg	3	3	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: Bravecto; Route: Topical / Cutaneous Was the product used ok?: Yes	12-Aug-2019	22-Aug-2019	10 days	D-D	As reported by the animal owner, 3 dogs, one 12 month old, intact, female, weighing 11 kg, and of good health, one 20 month old, intact, female, weighing 13 kg, and of good health, and one 4 year old, intact female, weighing 15 kg, and of good health (signalment otherwise unknown) were treated with FRONTLINE PLUS SPOT ON DOG M (batch number and expiry date unknown), correctly applied topically to an unknown site, by the animal owner, on 12 AUG 2019, as a parasiticide after seeing fleas. The owner reported that they were using Bravecto previously, but missed one dose and so the dogs picked up 1-2 fleas and now they have a home infestation. The owner lives near the woods where there is a high burden of fleas. The owner was recommended FRONTLINE PLUS by a large pet retailer last week, and they applied the product on 12 AUG 2019. The product was applied to all 3 dogs at the same time, and the owner is still seeing fleas. The numbers seem to be reducing but today (22 AUG 2019) they have noticed a large amount on her dogs. The owner has spoken to the vets and they have said it isn't working and that pets are becoming immune to the product. The owner is hoovering their home regularly and washing all soft furnishings.
22-Aug-2019	UAE; 19UK002758; -; United Kingdom	Species: Canine Breed: Lhasa Apso Sex: F Sex qualifier: Neutered Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: Advocate; Indorex; Route: unknown	Jul-2019*	Aug-2019*	N/A	D-D	As reported by the animal owner, Suki, a neutered, female, Lhasa Apso dog, weight and age unknown, and of good health was treated with FRONTLINE PLUS SPOT ON DOG M (batch number and expiry date unknown), details unknown, by the animal owner, for the past 2 months, for an unknown indication. The owner reported that prior to using FRONTLINE, they were using Advocate every month and never saw fleas then. After using the FRONTLINE PLUS the dog is riddled with fleas. The owner has been using FRONTLINE PLUS for now a month and a half so it should be working. Whilst the owner was on the phone they saw 3

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 232 of 867

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00239

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Was the product used ok?: Unknown to Company					fleas on the dog. The dog has flea dirt and flea allergy dermatitis and is constantly scratching. The owner took the dog to the groomers a few weeks ago but they said they didn't see any fleas or dirt. People in the house are being bitten, and they have sprayed the house with Indorex and vacuumed everywhere. On 28 AUG 2019 the owner reported that their dog is still scratching and itching and they can see loads of fleas in the coat. The dog breed means she has sensitive skin anyway but she is scratching herself so much she is making her skin red. On 12 SEP 2019 the animal owner reported that they are having an ongoing problem with trying to treat the dog for fleas. The animal is riddled with fleas and is scratching herself until she has sores. The animal owner reports that they could go to the vets but they will charge them lots of money. The animal owner says that it is the MAH's fault that they have a huge infestation - they have only seen one flea on them and six on their dog and think that the company should pay for a vet consultation. On 13 SEP 2019, the attending vet reported that the dog had been seen in practice, the dog has flea issues but no fleas were seen in consultation. The animal owner has seen many. The dog has dorsal alopecia and alopecia on the lateral aspect of the hind legs. There is some scabbing but no discharge. The attending vet suggested to recheck
22-Aug-2019	UAE; 19UK002759; MK41 9RA; United Kingdom	Species: Canine Breed: Spaniel (Cocker) Sex: M Sex qualifier: Unknown Age: 11.00 Year(s) Weight: Unknown	3	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: No (Treatment / vaccination program not respected)	11-Aug-2019	22-Aug-2019	0 Day(s)	D-D	As reported by the animal owner, an 11 year old, male Cocker Spaniel dog (signalment otherwise unknown) was treated with FRONTLINE SPOT ON DOG (estimated as FRONTLINE SPOT ON DOG M), details unknown, by the animal owner, on 11 AUG 2019, and again 2 weeks later (estimated as 22 AUG 2019), for an unknown indication. The owner reported that having had 3 dogs since 1981 when FRONTLINE came in, they have used this quite successfully, maintaining flea free dogs all the time with no problem. Since purchasing the last box on 10 AUG 2019, their dog has been over run with fleas with no let up. They owner does not take the dog for anything more than a short walk in their street, he does not go anywhere near parks, woods etc. or any other dogs. The owner is concerned that they have been unfortunate to have purchased a bad batch. The owner has purchased a whole load of powder for the house and shampoo for their poor, suffering dog. The owner reapplied the FRONTLINE 2 weeks after the application on 11 AUG 2019 as there was an infestation on him, and obviously FRONTLINE did not work. The dog has fortunately not suffered fleas at all in the past using a continual dose of FRONTLINE three months apart until now.
22-Aug-2019	UAE; 19UK002768; -, United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	12-Aug-2019	Aug-2019*	15 Day(s)	D-D	As reported by the animal owner, a cat (signalment otherwise unknown) was treated with FRONTLINE flea treatment (assumed FRONTLINE SPOT ON CAT, batch number, expiry date and further details unknown), by the animal owner, on 12 AUG 2019, for an unknown indication. The owner reported that they have been vacuuming carpets and furnishings daily. Since the treatment there are small, healthy looking fleas still jumping around on the cat. Case linked to 19UK002769.
22-Aug-2019	UAE; 19UK002769; -, United Kingdom	Species: Canine Breed: Canine (unknown)	1	1	0	Product used: FIPRONIL SPOT ON DOG	12-Aug-2019	Aug-2019*	0 days	D-D	As reported by the animal owner, a dog (signalment otherwise unknown) treated with FRONTLINE (estimated as FRONTLINE SPOT ON DOG M) batch number and expiry date unknown, details

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 233 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00240

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex: U Sex qualifier: Unknown Age: - Weight: Unknown				Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company					unknown, by the animal owner, on 12 AUG 2019, for an unknown indication. The owner reported that they have been vacuuming carpets and furnishings daily. The dog is still scratching and grooming excessively since it was treated. Case linked to 19UK002768.
22-Aug-2019	UAE; 19UK002770; -; United Kingdom	Species: Canine Breed: Spaniel Sex: M Sex qualifier: Unknown Age: 14.00 Month(s) Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	22-Aug-2019	3 Day(s)	D-D	As reported by the animal owner, a 14 month old, male, Spoodle (springer spaniel cross poodle) dog (signalment otherwise unknown) was treated with FRONTLINE SPOT ON (estimated as FRONTLINE SPOT ON DOG M), batch number and expiry date unknown, details unknown, by the animal owner, on 19 AUG 2019, for an unknown indication. The owner reported that the dog is still being driven mad with fleas, they think that's what they are as they have seen them moving fast on the dog's tummy.
23-Aug-2019	UAE; 19UK002773; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: X Sex qualifier: Neutered Age: - Weight: Unknown	4	4	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: FIPRONIL SPOT ON CAT; Route: Topical / Cutaneous Was the product used ok?: Yes	Feb-2019*	2019*	4 Day(s)	D-D	As reported by the animal owner, Mia, Lulu and Shadow, all neutered female cats, and Dexter, a neutered, male cat (signalment otherwise unknown) were treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), correctly administered topically to an unknown site, by the animal owner, for the past 6 months, with the last application on 23 AUG 2019, for an unknown indication. The owner reported that they have used FRONTLINE SPOT ON CAT (batch number and expiry date unknown) for a number of years and then moved to FRONTLINE PLUS 6 months ago. The product was applied correctly, every 4 weeks as advised, but the owner is not happy about the fact that they are still seeing fleas (only 1 or 2).
23-Aug-2019	UAE; 19UK002778; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a cat (signalment otherwise unknown) was treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), details unknown, by the animal owner, on an unknown date, for an unknown indication. The owner reported that this is the second lot of FRONTLINE they have purchased and it did not work at all. The owner reported that they complained to the chemist they bought it from and they said they had loads of complaints because it did not work. The owner was informed this was a strong product and does the job, but the first one did not and so they tried again with the result of nothing. Start date of event added for submission purposes only.
23-Aug-2019	UAE; 19UK002780; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used	N/A	2019*	N/A	D-D	As reported by the animal owner, a dog (signalment otherwise unknown) was treated with FRONTLINE (estimated as FRONTLINE SPOT ON DOG M), batch number and expiry date unknown, details unknown, by the animal owner, on an unknown date, for an unknown indication. The owner asked if the FRONTLINE formula had been changed as they have been using the product for quite a few years with no problems but recently the dog has got fleas which had to be removed by hand over a 3 day period. On 05 SEP 2019 the animal owner reported that they have

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 234 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00241

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						ok?: Unknown to Company					spoken to quite a few dog owners who use FRONTLINE and have noticed a difference this year. The animal owner adds that they have tried a vinegar based shampoo to stop the fleas from attaching, but on checking daily still find one or two fleas. Start date of event added for submission purposes only.
23-Aug-2019	UAE; 19UK002782; -; United Kingdom	Species: Canine Breed: Spaniel (Cocker) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: No (Others)	N/A	Aug-2019*	0 Day(s)	D-D	As reported by the animal owner, 2 Cocker Spaniel dogs (breed interpreted from a typo in the original email, "Cockermouth panel", signalment otherwise unknown) were treated with FRONTLINE (estimated as FRONTLINE SPOT ON DOG M), details unknown, by the animal owner, every month, with the last application estimated as AUG 2019, for an unknown indication. The owner reported that the dogs have lots of fleas, that for some reason the dogs are covered and the can't seem to get rid of them. They have used a comb and shampoo daily but this is not moving them.
23-Aug-2019	UAE; 19UK002783; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: F Sex qualifier: Unknown Age: - Weight: Unknown	3	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: Indorex; Route: unknown Was the product used ok?: Unknown to Company	N/A	23-Aug-2019	1 Day(s)	D-D	As reported by the animal owner, 3 cats, including 1 female kitten (signalment otherwise unknown) were treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), details unknown, by the animal owner, on 22 AUG 2019, as a parasiticide. The owner reported that they noticed their kitten had fleas and so they applied the product to her and their 2 older cats. They have sprayed the whole house with Indorex, more than recommended. The owner reported that on 23 AUG 2019 they were still seeing fleas run through the kitten tonight and they have read this may be normal.
24-Aug-2019	UAE; 19UK002788; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a cat (signalment otherwise unknown) was treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), details unknown, by the animal owner, on an unknown date, for an unknown indication. The owner reported that FRONTLINE PLUS no longer works. The owner has tried 2 different batches, and neither worked. The owner reported that the fleas are now immune. The owner purchased the product from their chemist and now has to pay out again for a treatment that still works. Start date of event added for submission purposes only.
25-Aug-2019	UAE; 19UK002789; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: M Sex qualifier: Unknown Age: 10.00 Month(s) Weight: 9 lbs	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not	18-Jul-2019	Jul-2019	N/A	D-D	As reported by the animal owner, Romeo, a 10 month old male kitten, weighing 9 pounds (signalment otherwise unknown) was treated with FRONTLINE SPOT ON CAT (batch number: S21204BW, expiry date: AUG 2021), applied topically to the base of the skull and 2 cm further back, by the animal owner, on 18 JUL 2019, 01 AUG 2019 and 15 AUG 2019, for an unknown indication. The owner reported that they bought FRONTLINE from a large pet retailer and they have been so let down by the product. The owner always took their kitten to the vets prior to the FRONTLINE to be treated. The first time they used the FRONTLINE in JUL 2019 the cat still had fleas which spread in their home. The vet at the large pet retailer said they could use it again after 2 weeks but the owner continued to have a big problem. The owner has quarantined the kitten as the fleas have continued to bite him. The owner reported

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 235 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00242

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						respected)					that it has cost them hundreds and hundreds of pounds on their home trying to control the problem. The owner reported that in JUL 2019 and AUG 2019 they all noticed lots of flea bites to their feet and ankles, hence the reason they spent hundreds of pounds on home treatments. The cat is mainly an indoor cat until they noticed the fleas, then he was quarantined for the last 5 weeks as they needed to deal with their home. During these times the owner regularly combs their cat and has found up to 3 live fleas around his neck, however there is also continuous flea dirt and blood spots on him or around the home. The owner bathes Romeo usually after 5 days of giving treatment, they have lived in their house for 4 years, flea foggers have been used in each room twice in the last 5 weeks, a hot wash has been used for the bedding and clothes, and the owner also hoovered 3 times a day plus steaming. The owner has also used tins of flea sprays, powders, flea lamps and the hottest steamer they could buy. FRONTLINE PLUS was applied to the cat on 25 AUG 2019. On 03 SEP 2019 the animal owner reported that
25-Aug-2019	UAE; 19UK002790; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	8	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	25-Aug-2019	20 Day(s)	D-D	As reported by the animal owner, a cat (signalment otherwise unknown) was treated with FRONTLINE SPOT ON CAT (batch number and expiry date unknown), details unknown, by the animal owner, less than 21 days ago (estimated as 05 AUG 2019), for an unknown indication. The owner reported that less than 21 days after using the product they found a live flea on one of their cats. The cats had no contact with other animals and they have had no visitors etc. The owner has 8 cats. The owner has used cheaper products in the past that have worked much better than FRONTLINE did.
25-Aug-2019	UAE; 19UK002791; -; United Kingdom	Species: Canine Breed: Norfolk Terrier Sex: F Sex qualifier: Unknown Age: 3.00 Year(s) Weight: 6 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	2016	19-Aug-2019*	N/A	D-D	As reported by the animal owner, Betsy, a just over 3 year old, female, Norfolk Terrier dog weighing 6 kg (signalment otherwise unknown) was treated with FRONTLINE SPOT ON DOG S (batch number: S21209AW, expiry date: AUG 2021), topically to the back of the neck, by the animal owner, every month since she was a puppy (last application estimated as AUG 2019), for an unknown indication. The owner reported that this week they found that the dog had an infestation of fleas which not only caused Betsy and the owners huge distress, but also meant that they had to spend 2 whole days spraying the house and washing their clothes. The owner reported that they may need more spray. The owner reported that they have carried out the dosage instructions every month and to the letter. The owner took the dog to their normal vet who confirmed the flea infestation and sent photo proof to the retailer through which the FRONTLINE was bought. The owner's wife was bitten several times on her lower legs. The animal owner reports that they use the product monthly as indicated and all year round. The first time that they noticed fleas on their pet was 3 weeks after application and the last four days of application are 21 AUG 2019, 22 JUL 2019, 21 JUN 2019 and 22 MAY 2019. The animal spends time indoors and outdoors, all animals in the household and in contact animals have been treated and the animal owner is seeing far too many fleas to count on the animal. The animal owner reports that the animal never goes swimming but will get her paws wet but is not keen on swimming and the animal owner goes to the dog groomer every 6 months when she is bathed (last visit end MAY 2019). The animal owner has treated

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 236 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00243

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											the home with an environmental flea spray, washed the pet's bedding at over 60 degrees and regularly vacuumed all areas that the pet can access. On 04 SEP 2019 the animal owner reported that they have taken all the precautions and the animal has been treated with FRONTLINE SPOT ON every month
25-Aug-2019	UAE; 19UK002792; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, 2 cats (signalment otherwise unknown) were treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), details unknown, by the animal owner, on an unknown date, as a parasiticide. The owner reported that they recently bought the FRONTLINE PLUS to deal with the fleas that their 2 cats and 1 dog had picked up. 3 treatments were applied but the fleas have not gone. The owner has even used a house spray recommended by their vet. Start date of event added for submission purposes only. Case linked to 19UK002793.
25-Aug-2019	UAE; 19UK002793; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a dog (signalment otherwise unknown) was treated with FRONTLINE PLUS (estimated as FRONTLINE PLUS SPOT ON DOG M), batch number and expiry date unknown, details unknown, by the animal owner, on an unknown date, as a parasiticide. The owner reported that they recently bought the FRONTLINE PLUS to deal with the fleas their 2 cats and 1 dog had picked up. 3 treatments were applied but the fleas have not gone. The owner has even used a house spray recommended by their vet. Start date of event added for submission purposes only. Case linked to 19UK002792.
26-Aug-2019	UAE; 19UK002794; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: M Sex qualifier: Unknown Age: 10.00 Year(s) Weight: 3.9 - 4.1 kg	2	2	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	15-Aug-2019	09-Aug-2019	N/A	D-D	As reported by the animal owner, 2 cats (signalment otherwise unknown) were treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), details unknown, by the animal owner, on approximately 16 AUG 2019 and 26 AUG 2019, for an unknown indication. The owner reported that 10 days after first application, their cats still have fleas even after they combed them fully each day since the first application and now they have had to do it again, still with no success. The owner feels that the product doesn't work. UPDATE 24 SEP 2019: the animal owner added that the animals were Keith weighing 3.9 kg, and Elvis weighing 4.1 kg, both 10 year old male felines. They were administered FRONTLINE SPOT ON CAT, not FRONTLINE PLUS SPOT ON CAT as previously reported. The animal owner started using the product for their current flea issue on 15 AUG 2019 and the animal owner reports that they use the product every six weeks all year round. They first noticed fleas on 09 AUG 2019 and the last 4 dates of application were 29 AUG 2019, 15 AUG 2019, 04 JUL 2019 and 22 MAY 2019. The animal owner applies the product as directed to the back of the neck, people are being bitten in the home by fleas and the animals spend time indoors and outdoors. The animal owner is seeing many fleas - more than 5 at the same time, and the animals are never bathed or swim. The animal owner has treated the home with an environmental flea treatment (product unknown), washed the pet's bedding at over 60 degrees and regularly vacuumed all

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 237 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00244

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											areas that the pets can access.
26-Aug-2019	UAE; 19UK002795; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	N/A	26-Aug-2019	4 Day(s)	D-D	As reported by the animal owner, 2 dogs (signalment otherwise unknown) were treated with FRONTLINE PLUS SPOT ON DOG S (batch number and expiry date unknown), applied topically to the neck, by the animal owner, on 22 AUG 2019, for an unknown indication. The owner reported that they have signed up to a monthly subscription service from a large pet retailer. They administered it to both their dogs, and 4 days later they both have fleas. The owner regularly uses FRONTLINE and this is the first time it didn't work, perhaps its a faulty batch. UPDATE 27 SEP 2019: QA results received. Investigation completed for FIPRONIL 10%/S METHOPRENE 9% SPOT ON Lot Unknown, expiry. Case investigated by France - Toulouse. Final complaint evaluation An adverse event for Frontline Plus Dog, batch unknown, was received by BIAH QA on the 03 September 2019. Recurrence : This is the 20th complaints received for a LOE, in the past 12 months, all batches included of Frontline Plus Dog. The sample complaint is not received and requested. No pictures are attached for this case. This defect is rare, it represents 0.2 ppm of every batch produced in 2017 (17 complaints for 78 447 597 pipettes) (including all batches of Frontline Regular and Combo for Cats and Dogs/all ranges). Stability : the tests of stability are conform at the specifications. Quality issue : at this day, no knowledge of any known quality problem on the product. All batches produced are examined and deviation investigated, a release decision is taken among batch records review and quality control results. All released batches are conform with GMP and Marketing Authorization file. No impact for the quality of product and no impact for the market. This defect is categorized as major without impact on the market and is not justified.
26-Aug-2019	UAE; 19UK002800; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: 35 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: No (Low dose)	N/A	Aug-2019*	N/A	D-D	As reported by the animal owner, a canine weighing 35 kg (signalment otherwise unknown) was administered FRONTLINE PLUS SPOT ON DOG M (batch and expiry unknown, details unknown) by the animal owner for fleas. The animal owner reports that the treatment for fleas was based on a previous weight recording and it was the lower dose for dogs medium range. The animal owner is seeing active fleas 3 days after treatment and the animal's recent weight is 35 kg. The animal owner wants to apply another FRONTLINE dose for this weight. Start date added for submission purposes only.
27-Aug-2019	UAE; 19UK002804; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: FRONTLINE PETCARE HOME AND ENVIRONMENT FLEA SPRAY;	N/A	2019*	N/A	D-D	As reported by the animal owner, a cat (signalment otherwise unknown) was treated with FRONTLINE SPOT ON CAT (batch number and expiry date unknown), details unknown, by the animal owner, on an unknown date, for an unknown indication. The owner reported that they have followed the instructions to the letter and for the second time it fails to do what it says it's supposed to do. The cat is still suffering. The owner has also spent money on FRONTLINE PETCARE HOMEGARD HOUSEHOLD FLEA SPRAY (batch number and expiry date unknown) to spray their home, but the product does not work. The owner reported that the product is not fit for purpose. Start date of event added for

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 238 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00245

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Route: unknown Was the product used ok?: Unknown to Company					submission purposes only.
27-Aug-2019	UAE; 19UK002806; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: F Sex qualifier: Neutered Age: 10.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: Indirect Defense Spray; Bob Martin; Route: Topical / Cutaneous Was the product used ok?: Yes	02-Jul-2019*	Jul-2019*	N/A	D-D	As reported by the animal owner, Purdy, a 10 year old, small, neutered, female cat, breed unknown and of good health was treated with FRONTLINE SPOT ON CAT (batch number: S21509BX, expiry date: SEP 2021), correctly applied topically to the back of the neck, by the animal owner, 6/8 weeks ago (estimated as 02 JUL 2019), as a parasiticide. The owner reported that they have always used Bob Martin until two months ago. Their cat went to a cattery and came back with a lot of fleas so they switched to FRONTLINE SPOT ON. They have been using it for 6/8 weeks but are still seeing fleas and eggs within the home, mainly where the cat sleeps. The owner has been spraying the house with Indirect Defense Spray and has continued to treat the cat monthly but is concerned he is still seeing fleas and eggs. The owner has said that the amount is reducing though. The owner was being bitten at first, just once or twice, but not any more.
27-Aug-2019	UAE; 19UK002814; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	4	4	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: No (Treatment / vaccination program not respected)	20-May-2019	27-Aug-2019	12 Day(s)	D-D	As reported by the animal owner, 4 cats (signalment otherwise unknown) were treated with FRONTLINE SPOT ON CAT (batch number and expiry date unknown), details unknown, by the animal owner, on 20 MAY 2019 and 15 AUG 2019, for an unknown indication. The owner reported that they used FRONTLINE recently as a cheaper option than visiting their vets for their usual course of flea treatment. The owner has now treated all of the cats, correctly weighing them and using the right dose, now 2 weeks later the cats are carrying fleas. The owner is somewhat disappointed because they now not only are having to pay for a second treatment for each cat but they are also having to treat the house and as a precaution treat their 4 large breed dogs. The owner reported that the treatment has failed. The owner reported that its embarrassing to tell family and friends they may have left with a bite or two or that they have to check their animals when they've left. The dogs are bathed a minimal amount but are regularly groomed as 2 are long coat, a Border Collie and a German Shepherd. The dogs also enjoy swimming in the owner's local lake, but they do not swim within 48 hours after treatment. The owner hoovers twice on a daily basis both upstairs and down along with mopping with bleach and kennel scrub for the dog's sleeping area, and this is also used on their bedding, which is also washed weekly. The dogs are walked daily and have contact with other dogs. The cats are free to come and go as they please, and again, they are groomed but not bathed. Their bedding and scratch posts etc. are washed on a daily basis, unless needed. On 28 AUG 2019 the owner reported that they treated all of their animals, and on 15 AUG 2019, and two weeks later they still have live fleas on their animals, which are now within treatment. The owner firmly believes that this is down to the quality of the product or the lack there of. Case linked to 19UK002815.
27-Aug-2019	UAE; 19UK002815; -; United Kingdom	Species: Canine Breed: Canine various breeds Sex: U Sex qualifier:	4	4	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other	N/A	27-Aug-2019	N/A	D-D	As reported by the animal owner, one, 10 year old Staffordshire Bull Terrier dog, 1 Border Collie dog, 1 German Shepherd dog, and 1 dog of unknown breed (signalment otherwise unknown) were treated with FRONTLINE SPOT ON (estimated as FRONTLINE SPOT ON DOG L), batch number and expiry date unknown,

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 239 of 867

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00246

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Unknown Age: - Weight: Unknown				products Route: unknown Was the product used ok?: Unknown to Company					details unknown, by the animal owner, in AUG 2019, for an unknown indication. The owner reported that they used FRONTLINE recently as a cheaper option than visiting their vets for their usual course of flea treatment. The owner has now treated all of their 4 cats, correctly weighing them and using the right dose, now 2 weeks later the cats are carrying fleas. The owner is somewhat disappointed because they now not only are having to pay for a second treatment for each cat but they are also having to treat the house and as a precaution treat their 4 large breed dogs. The owner reported that the treatment has failed. The owner reported that its embarrassing to tell family and friends they may have left with a bite or two or that they have to check their animals when they've left. The dogs are bathed a minimal amount but are regularly groomed as 2 are long coat, a Border Collie and a German Shepherd. The owner also has to be particularly careful when it comes to flea treatment as their 10 year old Staffordshire Bull Terrier has a flea allergy. The dogs also enjoy swimming in the owner's local lake, but they do not swim within 48 hours after treatment. The owner hooovers twice on a daily basis both upstairs and down along with mopping with bleach and kennel scrub for the dog's sleeping area, and this is also used on their bedding, which is also washed weekly. The dogs are walked daily and have contact with other dogs. The cats are free to come and go as they please, and again, they are groomed but not bathed. Their bedding and scratch posts etc. are washed on a daily basis, unless needed. On 28 AUG 2019 the owner reported that they treated all of their animals, and on 15 AUG
27-Aug-2019	UAE; 19UK002816; -, United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	N/A	26-Aug-2019*	0 Day(s)	D-D	As reported by the animal owner, a dog (signalment otherwise unknown) was treated with FRONTLINE PLUS (estimated as FRONTLINE PLUS SPOT ON DOG M), batch number and expiry date unknown, applied topically to an unknown site, by the animal owner, twice in the last week, with the last application estimated as on 26 AUG 2019, for an unknown indication. The owner reported that FRONTLINE PLUS is not working on his dog as the dog still has fleas after the 2 applications this week. Nobody is being bitten in the home.
27-Aug-2019	UAE; 19UK002817; -, United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used	27-Jul-2019	Jul-2019*	N/A	D-D	As reported by the animal owner, a dog (signalment otherwise unknown), was treated with FRONTLINE PLUS SPOT ON DOG L (batch number: S63225AL, expiry date: OCT 2021), applied topically to an unknown site, by the animal owner, 5 times within a 2 week and 3 day period, starting on 27 JUL 2019 and ending on 13 AUG 2019, for an unknown indication. The owner reported that they were still seeing fleas on their dog, and family members were being bitten. The owner wanted to know if the batch was a dodgy batch as it was not working properly. The owner purchased the product online, but they were unsure of the exact website. The owner is also applying spray to the house which was also bought online, to try and control the infestation. The dog's bedding is

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 240 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00247

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						ok?: No (Treatment / vaccination program not respected)					washed every day. UPDATE 09 Oct 2019: QA results received. Investigation completed for FIPRONIL 10%/S METHOPRENE 9% SPOT ON Lot S63225AL, expiry 2021-10-31. A product quality complaint for Frontline Dog batch S63225AL was received by BIAH QA on 06th September 2019. The complaint description is lack of efficacy. This is the first complaint regarding this defect for this batch. The retention sample is conform (aspect). The sample complaint is not received and no requested; No pictures attached for this case. Batch record investigation: Bulk batch: S632 Manufacturing date: 13/11/2018 - Expiry date: 10/2021 - Manufacturing quantity: 2400 liters No deviation and observation are associated to this batch. This batch was not concerned by any change control. The results of QC testing are conform at specifications (title on fipronil and methoprene). All parameters verified during manufacturing of this batch of bulk are conform. Filling batch: S63225. Manufacturing date: 05/12/2018 - Expiry date: 10/2021 - Manufacturing quantity: 13570 blisters of 3 pipettes. No deviation is associated to this batch. Two observations not associated to this defect. This batch was not concerned by any change control. The results of QC testing are
27-Aug-2019	UAE; 19UK002818; -, United Kingdom	Species: Canine Breed: Yorkshire Terrier Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	Jul-2019*	Aug-2019*	0 Day(s)	D-D	As reported by the animal owner, a Yorkshire Terrier dog (signalment otherwise unknown) was treated with FRONTLINE PLUS (estimated as FRONTLINE PLUS SPOT ON DOG S), batch number and expiry date unknown, details unknown, by the animal owner, for the last month, as a parasiticide. The owner reported that they still have lots of flea activity and their poor dog is still infested. The owner is yet to come across a flea that is dead or dying.
27-Aug-2019	UAE; 19UK002819; -, United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON; Route: unknown Was the product used ok?: Unknown to Company	N/A	Aug-2019*	31 Day(s)	D-D	As reported by the animal owner, a dog (signalment otherwise unknown) was treated with FRONTLINE SPOT ON (estimated as FRONTLINE SPOT ON DOG M), batch number and expiry date unknown, details unknown, by the animal owner, regularly, for an unknown indication. The owner reported that they have treated their cat as well with FRONTLINE, but they noticed this month that the dog had some fleas, so they went to the store where they bought the FRONTLINE SPOT ON and they recommended FRONTLINE PLUS (estimated as FRONTLINE PLUS SPOT ON DOG M). The owner treated both animals a fortnight ago (estimated as 13 AUG 2019) but the dog is still suffering, they've just picked 10 fleas off her.
27-Aug-2019	UAE; 19UK002821; -, United Kingdom	Species: Canine Breed: Dachshund Sex: M Sex qualifier: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products	N/A	20-Aug-2019	1 Week(s)	D-C	As reported by the animal owner, a male Daschund dog (signalment otherwise unknown) was treated with FRONTLINE (estimated as FRONTLINE SPOT ON DOG S), batch number and expiry date unknown, details unknown, by the animal owner, 2 weeks ago (estimated as 13 AUG 2019), for an unknown indication. The owner reported that they used the FRONTLINE pipettes for the first time after using 2 years of tablets from the

N/A signifies the information for this field is either not available or not applicable

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

Report printed on 25-Oct-2019 at 8:39:59PM

*indicates Approximate date or weight

Page 241 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00248

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: - Weight: Unknown				Route: unknown Was the product used ok?: Unknown to Company					vets. After a week of using FRONTLINE, they noticed that the dog was scratching a lot more than usual, and now 2 weeks later most of his back is covered in scabs and is bleeding from his scratching. The owner has been advised that the dog could be allergic. The owner has used medicated talcum and Sudocrem but to no avail.
27-Aug-2019	UAE; 19UK002826; -, United Kingdom	Species: Feline Breed: Feline (unknown) Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a male cat (signalment otherwise unknown) was treated with FRONTLINE SPOT ON CAT (batch number and expiry date unknown), details unknown, by the animal owner, monthly, as a parasiticide. The owner reported that FRONTLINE does not kill the fleas on their cat. He was infested when they took him to the vets. The owner buys a prescribed repellent from the vet now. The owner's veterinary surgeon told them that over the counter repellents do not have strong enough ingredients to kill the fleas, therefore should not be sold. The owner uses FRONTLINE on their cat monthly as instructed on the packaging. Start date of event added for submission purposes only.
27-Aug-2019	UAE; 19UK002827; -, United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	09-Aug-2019*	0 Day(s)	D-D	As reported by the animal owner, a cat (signalment otherwise unknown) was treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), details unknown, by the animal owner, on 09 AUG 2019, for an unknown indication. The owner reported that they have a cat and a dog and both were given FRONTLINE PLUS 18 days ago, but they still have fleas, not as many, but the cat is still scratching. The house has been sprayed, everything has been washed at 90 degrees Celsius, and the owner has hoovered everyday. Case linked to 19UK002829.
27-Aug-2019	UAE; 19UK002829; -, United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	09-Aug-2019*	0 Day(s)	D-D	As reported by the animal owner, a dog (signalment otherwise unknown) was treated with FRONTLINE PLUS SPOT ON DOG (estimated as FRONTLINE PLUS SPOT ON DOG M), batch number and expiry date unknown, details unknown, by the animal owner, on 09 AUG 2019, for an unknown indication. The owner reported that they have a cat and a dog and both were given FRONTLINE PLUS 18 days ago, but they still have fleas, not as many, but the cat is still major scratching. The house has been sprayed, everything has been washed at 90 degrees Celsius, and the owner has hoovered like mad everyday. Case linked to 19UK002827.
27-Aug-2019	UAE; 19UK002830; -, United Kingdom	Species: Canine Breed: Canine (unknown) Sex: F Sex qualifier: Unknown Age: - Weight: 4.5 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	27-Aug-2019	6 Day(s)	D-D	As reported by the animal owner, a female dog, weighing 4.5 kg (signalment otherwise unknown) was treated with FRONTLINE flea and tick spot on (assumed FRONTLINE SPOT ON DOG S, batch number and expiry date unknown), details unknown, by the animal owner, on 21 AUG 2019, for an unknown indication. The owner reported that on 27 AUG 2019 they noticed a live flea and the dog is still scratching non-stop.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 242 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00249

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
27-Aug-2019	UAE; 19UK002831; -, United Kingdom	Species: Feline Breed: Feline (unknown) Sex: F Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	May-2019*	2019*	N/A	D-D	As reported by the animal owner, a female feline (signalment otherwise unknown) was administered FRONTLINE PLUS SPOT ON CAT (batch, expiry, and details unknown) topically to the bottom of the neck by the animal owner, to keep her free from fleas, ticks and lice. The animal owner bought the product on 19 AUG 2019 and is disgusted that the product doesn't actually work. Their cat still has fleas and in turn, has caused their house to become infested. The product is supposed to have stopped this and now they have to sort out their house where their child lives. The animal owner reports that they started using the product in MAY 2019 when they let the animal out and applied it by separating the fur at the bottom of the neck until the skin was visible. The animal owner reports that the product is not killing the fleas on the animal and that they are becoming fully grown and laying eggs. It is stressful as the animal owner and their son are being bitten. The animal owner only has one pet. Start date added for submission purposes only.
27-Aug-2019	UAE; 19UK002832; -, United Kingdom	Species: Canine Breed: Canine (various breeds) Sex: X Sex qualifier: Neutered Age: - Weight: Unknown	9	9	0	Product used: FIPRONIL SPRAY Other products used: Bob Martin Spot On; Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	2015*	27-Aug-2019	0 Day(s)	D-D	As reported by the animal owner, a total of 9, male and female, Labrador Retriever and Cocker Spaniel dogs (signalment otherwise unknown) were treated with FRONTLINE SPRAY (batch number: 502306A, expiry date: AUG 2021), applied topically, by the animal owner, every week, for the past 4 years, with the last application on 27 AUG 2019, for an unknown indication. The owner reported that they have never had a problem with FRONTLINE SPRAY before, but it has now stopped working. The owner is convinced it doesn't work. The 500 ml spray is being used on all the dogs as well as Bob Martin Spot On.
27-Aug-2019	UAE; 19UK002833; -, United Kingdom	Species: Feline Breed: Feline (various breeds) Sex: F Sex qualifier: Unknown Age: 3.00 Month(s) Weight: 2 - 4 kg	3	3	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	Aug-2018*	26-Aug-2019*	12 Day(s)	D-D	As reported by the animal owner, a 2 year old, female, Domestic Longhair cat, weighing 4 kg, a 3 month old, female, Domestic Longhair kitten, weighing 2 kg, and a 3 month old, female, Domestic Shorthair kitten, weighing 2 kg (signalment otherwise unknown) were treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), applied topically between the shoulder blades, by the animal owner, every month for the past year, with the last treatments on 13 MAY 2019, 15 JUN 2019, 10 JUL 2019, and 14 AUG 2019, for an unknown indication. The owner reported that this was the 2 kitten's first treatment, but the mum cat and their Staffordshire Bull Terrier dog have been using it for the past year. The owner reported that the first few days after the most recent treatment on 14 AUG 2019 there were a lot of dead fleas, but now the infestation has gotten 10 times worse. The house has now basically become a breeding ground for fleas, and they've never had this issue before with the product. The owner uses the product all year round, every month without fail, and they noticed their current flea issue the other day (estimated as 26 AUG 2019), with there being hundreds of fleas everywhere. People in the house are being bitten and the owner's poor 4 year old looks like he permanently has chicken pox. Their pets spend time both indoors and outdoors, all animals in the house hold and all in contact animals have been treated with a flea product, the owner is

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 243 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00250

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											seeing many fleas, 5 or more at the same time, and the owner's pets never go swimming and never get bathed. The owner has lived in their house for more than a year and has treated the home with an environmental flea spray (product unknown), washed their pets bedding at over 60 degrees Celsius, and regularly vacuums all areas the pets can access. On 29 AUG 2019 the owner reported that they have never had this issue with the product before and that this time they've not even had to Hoover up dead fleas which they usually
27-Aug-2019	UAE; 19UK002834; -; United Kingdom	Species: Canine Breed: Staffordshire Terrier (American) Sex: F Sex qualifier: Unknown Age: 9.00 Year(s) Weight: 22 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	Aug-2018*	26-Aug-2019	12 Day(s)	D-D	As reported by the animal owner, a 9 year old, female, Staffordshire Bull Terrier dog, weighing 22 kg (signalment otherwise unknown) was treated with FRONTLINE PLUS SPOT ON DOG L (batch number and expiry date unknown), applied topically between the shoulder blades, by the animal owner, every month for the past year, with the last treatments on 13 MAY 2019, 15 JUN 2019, 10 JUL 2019, and 14 AUG 2019, for an unknown indication. The owner reported that the first few days after the most recent treatment on 14 AUG 2019 there were a lot of dead fleas, but now the infestation has gotten 10 times worse. The house has now basically become a breeding ground for fleas, and they've never had this issue before with the product. The owner uses the product all year round, every month without fail, and they noticed their current flea issue the other day (estimated as 26 AUG 2019), with there being hundreds of fleas everywhere, and it appears the issue has got 10x worse. People in the house are being bitten and the owner's poor 4 year old looks like he permanently has chicken pox. Their pets spend time both indoors and outdoors, all animals in the house hold and all in contact animals have been treated with a flea product, the owner is seeing many fleas, 5 or more at the same time, and the owner's pets never go swimming and never get bathed. The owner has lived in their house for more than a year and has treated the home with an environmental flea spray, washed their pets bedding at over 60 degrees Celsius, and regularly vacuums all areas the pets can access. On 29 AUG 2019 the owner reported that they have never had this issue with the product before and that this time they've not even had to Hoover up dead fleas which they usually have to do. The owner is concerned there was an issue with the batch. Case linked to 19UK002833 as a SLEE was reported for the cat in the household as well.
27-Aug-2019	UAE; 19UK002835; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a male dog (signalment otherwise unknown) was treated with FRONTLINE SPOT ON (estimated as FRONTLINE SPOT ON DOG M), batch number and expiry date unknown, details unknown, by the animal owner, on an unknown date, for an unknown indication. The owner reported that they used FRONTLINE SPOT ON, then their dog got a tick, so they went to a large pet retailer, and they gave them FRONTLINE PLUS. The outcome is unknown. Start date added for submission purposes only.
27-Aug-2019	UAE; 19UK002836; -; United Kingdom	Species: Canine Breed: Canine various breeds Sex: U Sex qualifier: Mixed	2	2	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products	Apr-2019	21-Jul-2019	0 Day(s)	D-D	As reported by the animal owner, George, a 7 year old, neutered, Sprocker dog, sex unknown, weighing 27 kg and of good health, and Cash, a 3 year old, intact, Greek Harehound dog, sex unknown, weighing 33 kg, and of good health were treated with FRONTLINE SPOT ON DOG L (batch number: R21901BR, expiry date: NOV 2020), applied topically to an unknown site, by the

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 244 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00251

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: 3.00 Year(s) Weight: 27 - 33 kg				Route: Topical / Cutaneous Was the product used ok?: Yes					animal owner, on 21 JUL 2019, as a parasiticide. The owner reported that there was a gap of 3 months without flea treatment before this application, with the last application before this in APR 2019. The FRONTLINE was applied on 21 JUL 2019 when fleas were seen on both dog's coats/ Nobody in the house is being bitten. UPDATE RECEIVED FROM AUTHORITY 03 OCT 2019: Authority assessment N. Changed in MAH case. No other changes.
27-Aug-2019	UAE; 19UK002838; -; United Kingdom	Species: Canine Breed: Border Collie Sex: U Sex qualifier: Unknown Age: 11.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	Jun-2019*	Jun-2019*	0 Day(s)	D-D	As reported by a sales representative, an 11 year old, Border Collie dog (signalment otherwise unknown) was treated with FRONTLINE PLUS SPOT ON DOG L (batch number and expiry date unknown) details unknown, by the animal owner, with 3 doses applied around JUN 2019, for an unknown indication. The owner reported that the dog had been poorly earlier this year, suffering with an enlarged heart and fluid on the lungs, and the dog is now on daily tablets for its heart and water, however the illness is not connected to the FRONTLINE PLUS as it happened before it was applied. The owner applied 3 pipettes and they had no effect on killing fleas. She took the dog to the vets who administered a tablet which cured the problem. The tablet or active ingredient begins with an 's' but the owner can't remember the exact name. The owner said she had treated her house and understood that FRONTLINE makes fleas hyperactive as she is an SQP. There are no batch details as the owner has disposed of the packaging.
28-Aug-2019	UAE; 19UK002844; -; United Kingdom	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: M Sex qualifier: Neutered Age: 15.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	14-Aug-2019*	28-Aug-2019	N/A	D-D	As reported by the animal owner, Sooty, a 15 year old, very large, neutered, male, Domestic Shorthair cat, exact weight unknown, and of fair health was treated with FRONTLINE SPOT ON CAT (batch number: F20308AW, expiry date: FEB 2021), applied topically to an unknown site, by the animal owner, 2 weeks ago (estimated as 14 AUG 2019), as a parasiticide. The owner reported that they had never used a flea product before but saw fleas 2 weeks ago and applied FRONTLINE SPOT ON. The owner is still seeing fleas and believes it isn't working. The owner has been bitten once, but nobody else in the household has and she is seeing on average 2-3 fleas a day. The owner believes that next door's cat has fleas and is passing them to her cat. The owner is using a home spray from the vet and is vacuuming every other day.
28-Aug-2019	UAE; 19UK002845; -; United Kingdom	Species: Canine Breed: Retriever Labrador Sex: M Sex qualifier: Neutered Age: 6.00 Year(s) Weight: 38 - 45 kg	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Yes	N/A	2019*	N/A	D-D	As reported by the animal owner, Milo, a 6 year old, neutered, male Labradoodle dog, weighing 45 kg, and of good health, and Albert, a 6 year old, neutered, male, Labradoodle dog, weighing 38 kg and of good health were treated with FRONTLINE PLUS SPOT ON DOG L (batch number and expiry date unknown), details unknown, by the animal owner, every month, all year round with the last application on 14 AUG 2019, for an unknown indication. The owner reported that they are still seeing fleas. They have always used the product all year round and have been compliant. The dog's bedding is sprayed with homemade essential oils. Start date of event added for submission purposes only.
28-Aug-2019	UAE; 19UK002848; -; United Kingdom	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: X	2	1	0	Product used: FIPRONIL SPRAY Other products used: no other	27-Aug-2019	28-Aug-2019	1 Day(s)	D-D	As reported by the animal owner, Bardon, a 2 year old, neutered, male, Domestic Shorthair cat, and Bella, a 2 year old, neutered, female, Domestic Shorthair cat (signalment otherwise unknown) were treated with FRONTLINE SPRAY (batch number and expiry date unknown), applied topically, by the attending veterinary

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 245 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00252

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: Neutered Age: 2.00 Year(s) Weight: Unknown				products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company					surgeon, on 27 AUG 2019, for an unknown indication. The owner reported that on 28 AUG 2019 Bella was vomiting liquidy stuff and then this afternoon was just foaming at the mouth, with lots of saliva. The owner called the vet practice who said to call Boehringer.
28-Aug-2019	UAE; 19UK002850; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	3	3	0	Product used: FIPRONIL SPOT ON CAT Other products used: FRONTLINE PETCARE HOME AND ENVIRONMENT FLEA SPRAY; Route: unknown Was the product used ok?: No (Treatment / vaccination program not respected)	Jun-2019*	2019*	0 Day(s)	D-D	As reported by the animal owner, 3 cats (signalment otherwise unknown) were treated with FRONTLINE SPOT ON CAT (batch number and expiry date unknown), details unknown, by the animal owner, on an unknown date, for an unknown indication. The owner reported that their 3 cats have fleas and their house is now infested. Over the past 2 months the owner has purchased 3 FRONTLINE SPOT ON treatments and each cat has had in total 6 pipettes and are still covered in fleas. The owner has also bought 5 cans of FRONTLINE PETCARE HOMEGARD HOUSEHOLD FLEA SPRAY (batch number and expiry date unknown) which have done nothing at all. The owner is now going to have to pay for their house to be fumigated and their cats will have to go to the vets to be properly treated.
28-Aug-2019	UAE; 19UK002851; UK; United Kingdom	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: X Sex qualifier: Neutered Age: 2.00 Year(s) Weight: Unknown	2	2	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	14-Aug-2019	28-Aug-2019	N/A	D-D	As reported by the animal owner, Dexter, a 17 year old, neutered, male, Domestic Shorthair cat, weight unknown, and of good health, and Staffie, a 2 year old, neutered, female, Domestic Shorthair cat, weight unknown, and of good health were treated with FRONTLINE SPOT ON CAT (batch number and expiry date unknown), applied topically to an unknown site, by the animal owner, twice in the past 2 weeks, with the first ever application 2 weeks ago (estimated as 14 AUG 2019), as a parasiticide. The owner reported that they purchased the FRONTLINE SPOT ON from the chemist and used it on both of their cats after they had gotten fleas. The cats are inside cats but the owner has been around other cats and thinks he may have brought them in. The cats were not treated at all before the 14 AUG 2019. The owner stated that the product isn't working at all and his cats are covered in fleas and eggs. The owner is not being bitten yet but can see lots of fleas and eggs. The owner is vacuuming and cleaning regularly and has ordered a fog product for each room to treat the house. The owner stated that he believes the product is distressing his cats. This case is classified as both 'SLEE' and 'Adverse Reaction' but due to a limitation of the database it might be that only the highest hierarchical product problem type, which is 'Adverse Reaction', has been transmitted.
28-Aug-2019	UAE; 19UK002852; -; United Kingdom	Species: Feline Breed: Feline various breeds Sex: X Sex qualifier: Unknown Age: 12.00 Year(s)	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other	27-May-2019	Jul-2019*	N/A	D-D	As reported by the animal owner, Marmalade, a 12 year old, female, Moggie cat (cross breed), weighing 4.5 kg and Mr D'Arcy, a 12 year old, male, British Blue cat, weighing 6 kg (signalment otherwise unknown) were treated with FRONTLINE PLUS SPOT ON CAT (batch number: R40718AW, expiry date: JUN 2020), applied topically to an unknown site, by the animal owner, all year round, every 8 weeks in the winter and then monthly from MAY to

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 246 of 867

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00253

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: 4.5 - 6 kg				products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company					about SEP, with the last applications on 27 MAY 2019, 24 JUN 2019, 22 JUL 2019, and 19 AUG 2019, for an unknown indication. The owner reported that they are still seeing fleas, and that they have been bitten a few times. The owner also has 2 dogs which were also treated and have also still got fleas (case 19UK002853). The owner first noticed the fleas in JUL 2019, all the pets go both indoors and outdoors, all animals in the household including all in contact animals have been treated with a flea product, and the owner is seeing 6-10 fleas roughly. None of the animals swim or are bathed, the owner has lived in their house for 6 years, and they have vacuumed all areas the pets can access and washed all the pets bedding.
28-Aug-2019	UAE; 19UK002853; -; United Kingdom	Species: Canine Breed: Canine various breeds Sex: X Sex qualifier: Unknown Age: 1.00 Year(s) Weight: 17 - 19 kg	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	27-May-2019	Jul-2019*	N/A	D-D	As reported by the animal owner, Algae, a 7 year old, female, Springer Spaniel dog, weighing 17 kg and Harry, a 1 year old, male, Collie dog, weighing 19 kg (signalment otherwise unknown) were treated with FRONTLINE PLUS SPOT ON DOG M (batch number: S61707AL, expiry date: JUN 2021), applied topically to an unknown site, by the animal owner, all year round, every 8 weeks in the winter and then monthly from MAY to about SEP, with the last applications on 27 MAY 2019, 24 JUN 2019, 22 JUL 2019, and 19 AUG 2019, for an unknown indication. The owner reported that they are still seeing fleas, and that they have been bitten a few times. The owner also has 2 cats which were also treated and have also still got fleas (case 19UK002852). The owner first noticed the fleas in JUL 2019, all the pets go both indoors and outdoors, all animals in the household including all in contact animals have been treated with a flea product, and the owner is seeing 6-10 fleas roughly. None of the animals swim or are bathed, the owner has lived in their house for 6 years, and they have vacuumed all areas the pets can access and washed all the pets bedding.
28-Aug-2019	UAE; 19UK002854; UK; United Kingdom	Species: Canine Breed: Bichon Frise Sex: M Sex qualifier: Unknown Age: 5.50 Year(s) Weight: 10 kg*	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, Billy a male Bichon Frise dog aged 5.5 years and weighing less than 10 kg (signalment otherwise unknown) was treated with FRONTLINE PLUS SPOT ON DOG S, batch number: S60328AL, expiry date: JAN 2021, in JUN 2019 (further details unknown), by the animal owner, on an unknown date, as a parasiticide after seeing fleas. The owner reported that they are seriously concerned that FRONTLINE PLUS is not doing what it is advertised in their opinion. The owner has always owned dogs and they have never had one in all their years of owning them that has had fleas, but sadly this year their little Bichon picked up fleas either from the fields they assume they take him across or in the woods and parks near them. The owner was very concerned about this and was straight down to the pet shop to get some treatment for him. The owner is now on their second pack of FRONTLINE PLUS and are finding it does/did not kill fleas bearing in mind their little dog was not badly infested as they caught them, they thought straight away. The owner used the first pack as per instructions which didn't clear it so decided as we were advertising so much they would have to buy and try another pack of our expensive treatment. At the same time they were treating the house (product unknown), but it was the return of the fleas on the dog during the final treatment. The animal owner states that they have always had dogs but they have never had fleas, they use the product when they see fleas only, they first noticed fleas on their dog in JUN 2019 and this is also when they started using the product, and they have used the product according to the packet

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 247 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00254

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											instructions. People in the home are not being bitten by fleas, the dog spends time indoors and outdoors, all animals in the home have been treated with a flea product, they are seeing occasional fleas (less than 5 at a time), the dog is regularly groomed by a professional groomer and this is not within 2 days of product
28-Aug-2019	UAE; 19UK002855; -, United Kingdom	Species: Canine Breed: Canine various breeds Sex: X Sex qualifier: Unknown Age: 7.00 Year(s) Weight: 3.5 - 8.5 kg	6	6	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	N/A	10-Aug-2019*	3 Week(s)	D-D	As reported by the animal owner, Treacle a 10 year old male Patterdale Terrier cross Jack Russell Terrier canine weighing 8.5 kg, Marmite an 11 year old male Jack Russell Terrier canine weighing 6.5 kg, Scrabble an 11 year old female Jack Russell Terrier canine weighing 7.5 kg, Pumpkin a 9 year old male Chihuahua canine weighing 5 kg, Pernod a 9 year old female Chihuahua canine weighing 4.5 kg and Cadbury a 7 year old female Chihuahua canine weighing 3.5 kg, were administered FRONTLINE PLUS SPOT ON DOG S (batch S60812AL expiry MAR 2021) topically to the back of the neck, by the animal owner at an unknown dose on 20 JUL 2019 when the animals were seen scratching in JUL 2019. The animal owner reports that they applied FRONTLINE PLUS to all their dogs and also cleaned their beds and bedding and harnesses. All of their dogs are flea infested and scratching. This started about three weeks after the application. The animal owner groomed one animal today and has taken off more than six live fleas. The animal owner reports that they have more product to apply in SEP 2019 but needs to do something drastic as the situation is appalling and extremely disappointing. Previously the FRONTLINE has seemed to work well. The animal owner added that they took a picture of the hair removed from Pumpkin this afternoon and was flabbergasted to see that there were 12 live fleas visible in the fur, together with numerous specks, which may also be fleas. The animal owner has used the product on numerous occasions so feels confident that they have applied the contents of the pipette correctly however there is clearly an issue which they need help with and perhaps there is something that they have overlooked. The animal owner added that they boys would be delighted if they could rest easy and stop scratching incessantly. The animal owner reports that the product was used all last summer and was restarted in JUL 2019. All animals are treated at the same time, and a generally treated throughout
29-Aug-2019	UAE; 19UK002860; South Yorkshire; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: F Sex qualifier: Unknown Age: 12.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: FIPRONIL SPOT ON DOG; Route: unknown Was the product used ok?: Unknown to Company	N/A	25-Aug-2019	0 Day(s)	D-C	As reported by the animal owner, Poppy, a 12 year old female canine (signalment otherwise unknown) was administered FRONTLINE PLUS SPOT ON DOG S (batch S62713AW expiry SEP 2021) (details unknown) on 25 AUG 2019 for an unknown indication. The animal owner reports that on Sunday night the animal started being sick and had diarrhoea. After being up with the animal all night, this carried on for the Bank Holiday weekend every time she ate. On Tuesday (27 AUG 2019) after being very ill the animal owners took the animal to the vet who did various tests and concluded that she may have had an allergic reaction to the FRONTLINE. The animal continues to be ill but not as severely. The animal has always had FRONTLINE (assumed FRONTLINE SPOT ON DOG S) since being a puppy and is now 12 years old. The animal owner notices however that this has now become FRONTLINE PLUS, and wonders if the recipe has changed.
29-Aug-2019	UAE; 19UK002862; Lincolnshire; United Kingdom	Species: Rabbit Breed: Rabbit Other Sex: U	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products	28-Aug-2019	29-Aug-2019	1 Day(s)	D-B	As reported by a veterinary nurse, Leroy, a 2 year old, Mini Lop Rabbit (signalment otherwise unknown) was treated with FRONTLINE (estimated as FRONTLINE SPOT ON DOG M), batch number and expiry date unknown, details unknown, by the

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 248 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00255

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: Unknown Age: 2.00 Year(s) Weight: Unknown				used: no other products Route: unknown Was the product used ok?: No (Species not indicated / recommended)					animal owner, on 28 AUG 2019, for an unknown indication. The vet nurse reported that the owner called to say that they applied FRONTLINE SPOT ON to their dog and rabbit. 3 hours after application they washed it off the rabbit but the rabbit is now not eating and hasn't left its hutch. The rabbit has never been seen before by the practice and the owner did not get the FRONTLINE SPOT ON from the practice. The rabbit is coming in now to the practice.
29-Aug-2019	UAE; 19UK002865; -, United Kingdom	Species: Canine Breed: Terrier Breeds (500 Series) Sex: F Sex qualifier: Neutered Age: 6.00 Year(s) Weight: 11 lbs	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	19-Aug-2018*	2019*	N/A	D-D	As reported by the animal owner, Tammy, a 6 year old, neutered, female, Terrier Cross Breed dog, weighing 11 lb, and of good health was treated with FRONTLINE SPOT ON DOG M (batch number and expiry date unknown), correctly administered topically to the back of the neck, by the animal owner, every month, for the last 12 months, with the last application on 19 AUG 2019, as a preventative treatment. The owner reported that they have been using the treatment for the last 12 months with no gaps but lately the dog has started itching and scratching and the owner has been bitten several times, and believes the product isn't working. The owner has washed all the bedding and sprayed the home with a product from the vets. The owner lives on a farm so may be something other than fleas.
29-Aug-2019	UAE; 19UK002866; -, United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	3	3	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, 3 cats (signalment otherwise unknown) were treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), details unknown, by the animal owner, on an unknown date, for an unknown indication. The owner reported that all the cats had fleas and they used the product on all of the cats on the same day and at the same time. After a few days (estimated as 2) the owner reported that they noticed no difference so they washed them all with cat flea shampoo and nothing came out. The owner reported that the FRONTLINE didn't help one bit, and that they are very disappointed with the performance of the product. Start date of event added for submission purposes only.
29-Aug-2019	UAE; 19UK002867; -, United Kingdom	Species: Feline Breed: Feline (unknown) Sex: F Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	25-Aug-2019*	29-Aug-2019	4 Day(s)	D-D	As reported by the animal owner, a female cat (signalment otherwise unknown) was treated with FRONTLINE (assumed FRONTLINE SPOT ON CAT, batch number and expiry date unknown) details unknown, by the animal owner, 4-5 days ago (estimated as 25 AUG 2019), for an unknown indication. The owner reported that the cat still has fleas and eggs when they comb her.
29-Aug-2019	UAE; 19UK002869; Lincolnshire; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used	N/A	2019*	N/A	D-D	As reported by the animal owner, two canines (signalment otherwise unknown) were administered FRONTLINE (assumed FRONTLINE SPOT ON DOG M, batch, expiry and further details unknown) for an unknown indication. The animal owner reports that they have bought FRONTLINE for their two dogs for over 6 years. After treating one of their dogs twice with FRONTLINE it is as if no treatment has been used. Start date added for submission purposes only.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 249 of 867

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00256

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						ok?: Unknown to Company					
29-Aug-2019	UAE; 19UK002871; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a male cat (signalment otherwise unknown) was treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown) details unknown, by the animal owner, on two occasions (dates unspecified) for an unknown indication. The owner reported that they buy FRONTLINE PLUS for their cat and they still see fleas on their cat and the cat's skin was inflamed where bitten. The owner stated that the product doesn't work as they used a sachet and their cat still has the odd flea. Start date of event added for submission purposes only.
29-Aug-2019	UAE; 19UK002872; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	2	2	2	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-A	As reported by the animal owner, 2 male cats (signalment otherwise unknown) were treated with FRONTLINE SPOT ON CAT (batch number and expiry date unknown), details unknown, by the animal owner, for years, for an unknown indication. The owner reported that they had been recommended that they do not use FRONTLINE or any other flea treatment other than Advocate. The owner used FRONTLINE for years on their 2 boys, who have since sadly passed away, with no problem. The owner used Advocate once and one of their 3 kittens (assumed not the same animals as referred to using FRONTLINE) had a bad reaction to it (no further information provided). Start date of event added for submission purposes only.
29-Aug-2019	UAE; 19UK002873; -; United Kingdom	Species: Canine Breed: Border Terrier Sex: F Sex qualifier: Unknown Age: 8.00 Year(s) Weight: 9 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	14-Mar-2019	27-Aug-2019	5 Day(s)	D-D	As reported by the animal owner, Jess, an 8 year old female Border Terrier canine, weighing 9 kg and in unknown condition, was administered FRONTLINE SPOT ON DOG S (batch R62528AL expiry NOV 2020) topically to the base of the neck by the animal owner, at a dose of one dose every 8 weeks, most recently on 22 AUG 2019 for an unknown indication. The animal owner reports that they took the animal to the vet on 27 AUG 2019 as they suspected fits. The animal owner was dumbstruck when they were informed they were not fits but fleas. The animal owner reports that the animal never goes near other dogs. The animal owner reports that they use the product all year round and that the last four dates of administration were 14 MAR 2019, 08 MAY 2019, 01 JUL 2019 and 22 AUG 2019. No one in the house is being bitten and the animal spends time indoors and outdoors. All animals that live in the household and in-contact animals have been treated and the animal owner is seeing many fleas, more than 5 at the same time. The animal does not get bathed or swim within 2 days of product application and the animal owner has washed the pet's bedding at over 60 degrees and regularly vacuumed all areas that the pets can access.
29-Aug-2019	UAE; 19UK002874; -; United Kingdom	Species: Canine Breed: Akita Sex: F Sex qualifier: Unknown Age: 3.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the	N/A	2019*	3 days	D-B	As reported by the animal owner, a 3 year old female Akita dog (signalment otherwise unknown) was treated with FRONTLINE (estimated as FRONTLINE SPOT ON DOG, batch number, expiry date and further details unknown), by the animal owner, on an unknown date, for an unknown indication. The owner reported that they currently have a very sick dog after using FRONTLINE. The dog has been poisoned by it from what the owner and the vet presume. The animal owner asks if it is a possibility that their

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 250 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00257

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						product used ok?: Unknown to Company					animal could have been poisoned from the product. They report that from reading online there have been many cases of dogs becoming seriously ill after having a dose of FRONTLINE SPOT ON. The animal had her dose 3 days before being rushed into the vets with poisoning. The animal owner reports that up until then she was a happy, healthy 3 year old Akita. The animal owner states that the animal has a fifty percent survival rate. Start date of event added for submission purposes only.
29-Aug-2019	UAE; 19UK002875; -, United Kingdom	Species: Canine Breed: Collie Sex: F Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: Indorex; Route: unknown Was the product used ok?: Unknown to Company	N/A	Aug-2019*	29 Day(s)	D-D	As reported by the animal owner, 1 female Rough Collie dog, and 1 other Rough Collie dog (signalment otherwise unknown) were treated with FRONTLINE PLUS (estimated as FRONTLINE PLUS SPOT ON DOG M), batch number and expiry date unknown, details unknown, by the animal owner, on 01 AUG 2019, for an unknown indication. The owner reported that they have 2 cats and 2 dogs. They have been using FRONTLINE PLUS SPOT ON for their dogs but its not working. One of the dogs isn't too bad, but the other has a very thick coat and undercoat and she is riddled with fleas. The owner can see them crawling over her and there are poos everywhere on her. The fleas are worse since treatment. The house has been treated with Indorex, very thoroughly and the cats have also been treated with a flea product. The owner is considering using FRONTLINE SPRAY, which they used to use years ago on previous dogs, but their vet was concerned that it might not get through such a thick coat as a Rough Collie's. Case linked to 19UK002876.
29-Aug-2019	UAE; 19UK002876; -, United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: Indorex; Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	29 Day(s)	D-D	As reported by the animal owner, 2 cats (signalment otherwise unknown) were treated with FRONTLINE (estimated as FRONTLINE SPOT ON CAT), batch number and expiry date unknown, details unknown, by the animal owner, on an unknown date, for an unknown indication. The owner reported that they have 2 cats and 2 dogs. The owner's dogs are on FRONTLINE PLUS but its not working. The owner reported that the cats are using Stronghold as recommended by their vet, and they used to use FRONTLINE for them as well as the dogs, but again one cat had problems and also has Flea Allergy Dermatitis, so their vet recommended changing. The house has been treated with Indorex, very thoroughly. The owner is considering using FRONTLINE SPRAY. Start date of event added for submission purposes only. Case linked to 19UK002875.
30-Aug-2019	UAE; 19UK002877; -, United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	Feb-2019*	Aug-2019*	N/A	D-D	As reported by the animal owner, a cat (signalment otherwise unknown) was treated with FRONTLINE (estimated as FRONTLINE SPOT ON CAT), batch number and expiry date unknown, details unknown, by the animal owner, for the past 6 months (estimated start date as FEB 2019), for an unknown indication. The owner reported that they bought 6 months treatment for their cat and 6 months treatment for their dog, and they have used the lot and they still have fleas. Case linked to 19UK002878.
30-Aug-2019	UAE; 19UK002878; -, United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier:	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other	N/A	Aug-2019*	0 Day(s)	D-D	As reported by the animal owner, a dog (signalment otherwise unknown) was treated with FRONTLINE (estimated as FRONTLINE SPOT ON DOG M), batch number and expiry date unknown, details unknown, by the animal owner, for the past 6 months (estimated start date as FEB 2019), for an unknown

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 251 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00258

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Unknown Age: - Weight: Unknown				products Route: unknown Was the product used ok?: Unknown to Company					indication. The owner reported that they bought 6 months treatment for their cat and 6 months treatment for their dog, and they have used the lot and they still have fleas. Case linked to 19UK002877.
30-Aug-2019	UAE; 19UK002880; -, United Kingdom	Species: Canine Breed: Canine (unknown) Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a male dog (signalment otherwise unknown) was treated with FRONTLINE PLUS (estimated as FRONTLINE PLUS SPOT ON DOG M), batch number and expiry date unknown, details unknown, by the animal owner, twice, as a parasiticide. The owner reported that after spotting fleas recently on their pet dog the applied FRONTLINE PLUS, hoping that those on him would be dead within a short period of time. Whilst the number on him subsided for a short time, it was only around a week and a half later that he was re infested, with a large number of live fleas on him. The owner is aware that the environment plays a large part in re infestation, but the product claims to kill living fleas on the dog for up to a month, not 12 days. This occurrence has repeated even after re-treatment. The owner reported that the product is failing to control the flea population living in their dog. Start date of event added for submission purposes only.
30-Aug-2019	UAE; 19UK002881; -, United Kingdom	Species: Canine Breed: Spaniel (English Springer) Sex: M Sex qualifier: Unknown Age: - Weight: 20 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	2018*	2019*	N/A	D-D	As reported by the animal owner, Zak, a male English Springer Spaniel dog weighing 20 kg (signalment otherwise unknown) was treated with FRONTLINE PLUS SPOT ON DOG L, batch number and expiry date unknown, applied topically to the back of the neck, by the animal owner, monthly for well over a year (estimated dose start date as 2018), for an unknown indication. The owner reported that they are still seeing fleas on him. Start date of event added for submission purposes only.
30-Aug-2019	UAE; 19UK002884; -, United Kingdom	Species: Canine Breed: Shih Tzu Sex: U Sex qualifier: Unknown Age: 3.00 Year(s) Weight: 8.5 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	06-Jun-2019	2019*	N/A	D-D	As reported by the animal owner, Teddy, a 3 year old Shih Poo (Shih Tzu cross Poodle) canine, weighing 8.5 kg and in good condition, was administered FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG S, batch and expiry unknown) topically to an unknown site, by the animal owner, from 06 JUN 2019, at an unknown dose, for an unknown indication. The animal has fleas. The animal owner's husband is being bitten. The animal has been shaved and has no hair at the moment. The animal owner also has a cat, Marley a Domestic Short Hair weighing 6 to 7 kg and 9 years old. The cat has no fleas. Start date added for submission purposes only.
30-Aug-2019	UAE; 19UK002885; Berkshire; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier:	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other	N/A	16-Aug-2019	N/A	D-D	As reported by the attending veterinary surgeon, a canine weighing 9 kg (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON DOG S, batch and expiry unknown, dose details unknown) 2 weeks ago (16 AUG 2019) for an unknown indication. The attending vet states that the

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 252 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00259

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Unknown Age: - Weight: 9 kg				products Route: unknown Was the product used ok?: Unknown to Company					animal was given FRONTLINE 2 weeks ago and is riddled with fleas and there is lots and lots of flea dirt. The vet wants to give Bravecto. The animal owner has not mentioned being bitten and the vet has no idea where they purchased the product. The animal owner has treated the house but the vet is not sure what with, the owner has not mentioned swimming and the vet is not sure how often the animal is treated but thinks that the animal owner gives the animal FRONTLINE frequently. The vet reports that they went on holiday, came back with fleas, applied FRONTLINE and it hasn't worked.
30-Aug-2019	UAE; 19UK002888; Clwyd; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the veterinary nurse, a feline (signalment otherwise unknown) was administered FRONTLINE SPOT ON CAT (batch and expiry unknown) topically to the back of the neck, by the animal owner (details unknown) for an unknown indication. The veterinary nurse reports that the animal owner has been using FRONTLINE and got it from a pet shop. It doesn't seem to be working as the animal still has fleas. They want to use another spot on. Start date added for submission purposes only.
30-Aug-2019	UAE; 19UK002890; -, United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	30-Aug-2019	5 Day(s)	D-D	As reported by the animal owner, their 2 dogs (signalment otherwise unknown) were treated with FRONTLINE PLUS (assumed to be FRONTLINE PLUS SPOT ON DOG M) batch number and expiry date unknown, route and frequency unknown, administered by the dog's owner (date of administration estimated as 25 AUG 2019). On 30 AUG 2019 the owner reported that both the dogs were crawling with fleas. The owner reported that their house floor was mainly floorboards and that they were thoroughly cleaned, as was the dog's bedding. They had checked many pet forums and had spoken to their vet who had told them that FRONTLINE did not work anymore and that they did not recommend it. The owner had spent a large amount of money on the product and they were concerned that it was promoted as effective and was extremely costly. The animal owner added that they fully investigated how FRONTLINE and other flea treatments work and are fully aware that fleas can still jump onto the dog's coat. The animal owner is meticulous with regards to following the appropriate instructions regarding applying the treatment and not bathing the animal for a period of time. The animal owner is 100 percent sure that FRONTLINE is simply not working on both of the animal owner's dogs, as the flea problem would have reached infestation level if they had not taken action. If fleas are killed on the dog within 24 hours then the animal owner would expect to find some dead fleas on the dogs coat when using a flea comb, and this was simply not the case. The animal owner reported that both the animals are in excellent health and have had virtually no incidence of fleas in the past. Their bedding and all house floors, mostly sealed wood, are scrupulously cleaned every morning and evening. On the rare occasion that the animal owner has used flea treatment in the past it has worked in controlling and eradicating the problem. The animal owner adds that they now have to wait before they can use another treatment and in the mean time,
02-Sep-2019	UAE; 19UK002896;	Species: Feline Breed: Domestic	1	1	0	Product used: FIPRONIL SPOT	N/A	02-Sep-2019*	N/A	D-D	As reported by the animal owner, an 11 year old, female neutered, Domestic Shorthair cat (signalment otherwise unknown), was

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 253 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00260

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	-, United Kingdom	Shorthair (Crossbreed) Sex: F Sex qualifier: Neutered Age: 11.00 Year(s) Weight: Unknown				ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes					treated with FRONTLINE SPOT ON CAT (batch number and expiry date unknown), applied correctly, every 30 days, administered by the cat's owner, actual dates of administration unknown. On 02 SEP 2019 the owner reported that they were still seeing fleas. The owner had not been bitten, it was thought that they were possible hitchhiker fleas. The cat spent most of its time in the garden. The cat was the only animal the owner had.
31-Aug-2019	UAE; 19UK002897; -, United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	14	14	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	Jan-2019*	N/A	D-D	As reported by the animal owner, a foster rescuer, 14 cats (signalment otherwise unknown), were treated with FRONTLINE (assumed to be FRONTLINE SPOT ON CAT) batch number and expiry date unknown, administered by the owner, used for the last 13 years as their flea treatment. However, since JAN 2019 the owner had noticed a change in the SPOT ON as the cats were still getting fleas, it seemed not be as effective as it used to be, and did not tackle the fleas anymore, the animals were riddled. The owner was really disappointed that they have had to change brands, as they had used FRONTLINE for over 13 years, and they were a brand loyal person. It had also cost them nearly £110 a month. They waited 2 weeks before using another treatment. Linked case: 19UK002899. UPDATE 26 SEP 2019: QA results received. Investigation completed for FIPRONIL SPOT ON CAT Lot Unknown, expiry . Case investigated by France - Toulouse. Final complaint evaluation: An adverse event for FRONTLINE PLUS SPOT ON CATS, batch unknown, was received by BIAH QA on the 10th of September 2019. This is the 29th complaint received for this LOE, in the past 12 months, all batches of Frontline Cat. This defect is rare, it represents 0.2 ppm of every batch produced in 2017 (17 complaints for 78 447 597 pipettes) (including all batches of Frontline Regular and Combo for Cats and Dogs/all ranges). The complaint sample is not received and pictures are not attached to this case. Batch record investigation: Batch unknown. Root cause investigation: Stability: during the test of stability, we can observe that one batch out of thirteen an increase in the water content (regular cat). Efficacy, safety and quality of the product not in question because the whole dose is applied. The tests of stability are conform at the specifications. Quality issue : at this day, no knowledge of any known quality problem on the product. All batches produced are examined and deviation investigated, a release decision is taken among batch
31-Aug-2019	UAE; 19UK002898; -, United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	11-Jul-2019*	2019*	N/A	D-D	As reported by the animal owner, a feline (signalment otherwise unknown) was administered FRONTLINE PLUS SPOT ON CAT (batch and expiry unknown, details unknown) by the animal owner twice, one month apart with the last application on 11 AUG 2019, for an unknown indication. The animal owner reports that the animal still has fleas and queried if it was genuine as they have had no problems in the past with FRONTLINE until now. Start date added for submission purposes only.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 254 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00261

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
31-Aug-2019	UAE; 19UK002899; -; United Kingdom	Species: Canine Breed: German Shepherd Dog Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	4	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	Jan-2019*	N/A	D-D	As reported by the animal owner, a foster rescuer, 4 dogs, 1 of which was a German Shepherd dog (signalment otherwise unknown), were treated with FRONTLINE (assumed to be FRONTLINE SPOT ON DOG M) batch number and expiry date unknown, administered by the owner, used for the last 13 years as their flea treatment. However, since JAN 2019 the owner had noticed a change in the SPOT ON as their German Shepherd dog was riddled and was ripping it's fur. The FRONTLINE seemed not be as effective as it used to be, and did not tackle the fleas anymore, the animal was riddled. The owner was really disappointed that they have had to change brands, as they had used FRONTLINE for over 13 years. They waited 2 weeks before using another treatment. The owner also has 14 cats - see linked case: 19UK002897.
31-Aug-2019	UAE; 19UK002900; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: X Sex qualifier: Unknown Age: 1.00 Year(s) Weight: 2.5 - 3.5 kg	5	5	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	N/A	07-Aug-2019	0 Day(s)	D-D	As reported by the animal owner, Buster a 7 year old male feline weighing 3 kg, Violet a 7 year old female feline weighing 2.5 kg, Ollie, a 1 year old male feline weighing 3 kg, Lulu a 2 year old female feline weighing 2.5 kg and Daulton cat a 1 year old male feline weighing 3.5 kg, were administered FRONTLINE SPOT ON CAT (Batch and expiry unknown, details unknown) roughly three weeks ago (07 AUG 2019) for fleas. The animal owner bought the product for them all from the local vets. The animal owner reports that this was roughly three weeks ago yet all the fleas are still there and none of which have died. They have done the house also, but there are still fleas. The animal owner reports that they use the product monthly all year round so that they are always covered. People in the home are being bitten, the animals spend time indoors and outdoors and the animal owner is seeing many fleas - more than 5 at the same time. The animal owner has treated the home with an environmental flea treatment, washed the pets bedding at over 60 degrees and regularly vacuumed all areas that the pets can access. The animal owner also has two dogs which are reported in the linked case.
31-Aug-2019	UAE; 19UK002901; -; United Kingdom	Species: Canine Breed: Pug Sex: M Sex qualifier: Unknown Age: 1.00 Year(s) Weight: 11 - 14 kg	2	2	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	N/A	10-Aug-2019	N/A	D-D	As reported by the animal owner, Barry a 3 year old weighing 14 kg and Winston a 1 year old weighing 11 kg, both male Pug canines (signalment otherwise unknown) were administered FRONTLINE SPOT ON DOG M (Batch and expiry unknown) directly to the skin between the shoulder blades, roughly three weeks ago (07 AUG 2019) for fleas. The animal owner bought the product for from the local vets. The animal owner reports that this was roughly three weeks ago yet all the fleas are still there and none have died. They have done the house also, but there are still fleas. The animal owner reports that they use the product monthly all year round so that they are always covered. People in the home are being bitten, the animals spend time indoors and outdoors and the animal owner is seeing many fleas - more than 5 at the same time. The animal owner has treated the home with an environmental flea treatment, washed the pets bedding at over 60 degrees and regularly vacuumed all areas that the pets can access. The animal owner also has five cats, which are reported in the linked case 19UK002900.
31-Aug-2019	UAE; 19UK002902; -; United Kingdom	Species: Canine Breed: Chihuahua Sex: F Sex qualifier: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other	N/A	2019*	N/A	D-D	As reported by the animal owner, a female Chihuahua canine (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON DOG S, batch and expiry unknown, details unknown) by the animal owner for an unknown indication. The animal owner reports that since applying spot on to

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 255 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00262

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: - Weight: Unknown				products Route: unknown Was the product used ok?: Unknown to Company					their pet for the second time, she now seems to consistently scratch. They comb the animal with a flea comb and nothing shows but she won't stop scratching. The animal owner wonders if it is possible that she has got a reaction from the product. Start date added for submission purposes only.
31-Aug-2019	UAE; 19UK002903; -, United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: Unspecified house spray; Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	N/A	15-Aug-2019	0 Day(s)	D-D	As reported by the animal owner, a dog (signalment otherwise unknown), was treated with FRONTLINE SPOT ON (assumed to be FRONTLINE SPOT ON DOG M) batch number and expiry date unknown, frequency unknown, applied by the dog's owner on 15 AUG 2019 as flea treatment. On 31 AUG 2019 the owner reported that the dog still had fleas. They had sprayed the house with an unspecified treatment, but they were still unable to get rid of the fleas.
29-Aug-2019	UAE; 19UK002905; Hertfordshire; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: -	4	4	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	Feb-2019*	Feb-2019*	N/A	D-D	As reported by the animal owner, four felines (signalment otherwise unknown) were administered FRONTLINE PLUS SPOT ON CAT (batch and expiry unknown, details unknown) by the animal owner for the last six months (start date estimated FEB 2019) for fleas. They have four cats that they have flead for the second time in two months. They have been doing their cats each time. When they last did the cats, they had now been using FRONTLINE PLUS for 6 months on 4 cats. For the six months that the animal owner has been treating their cats, the FRONTLINE PLUS has not worked on their cats at all.
31-Aug-2019	UAE; 19UK002906; -, United Kingdom	Species: Feline Breed: Feline (unknown) Sex: M Sex qualifier: Unknown Age: 10.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	Aug-2019	0 Day(s)	D-B	As reported by the animal owner, an approximately 10 year old male feline (signalment otherwise unknown) was administered FRONTLINE PLUS SPOT ON CAT (batch S40310AW expiry JAN 2021) (details unknown) by the animal owner at a dose of 1 dose, in AUG 2019 for an unknown indication. The animal owner reports that the animal was originally a stray/feral and now has regular doses of FRONTLINE. In AUG 2019 they gave the animal a dose of FRONTLINE PLUS from a 6 x pipette pack, which resulted in virtual loss of fur on his back. Then for two days the animal suffered from seizures/fits resulting in the animal losing his balance and ending up on his back for seconds. The animal owner is extremely concerned that this should happen, but fortunately he seems to got over it. The animal owner states that as another pipette will be due in SEP 2019 they are concerned that there might be a recurrence of this. The animal owner reported that they took the animal to the vet who said that if they required another brand of flea killer they had to weigh the cat and they could issue a prescription. UPDATE 27 SEP 2019: QA results received. Investigation completed for FIPRONIL 10%/S METHOPRENE 12% SPOT ON Lot S40310AW, expiry 2021-01-31. Case investigated by France - Toulouse. Final complaint evaluation: A product quality complaint for FRONTLINE SPOT ON CAT batch S40310AW was received by

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 256 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00263

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											<p>BIAH QA on 12th September 2019. The complaint description is adverse event. This is the second complaint regarding this defect for this batch</p> <p>The retention sample is conform (aspect). The sample complaint is not received no pictures are attached for this case. Batch record investigation: Bulk batch: S403. Manufacturing date: 13/02/18 - Expiry date: 07/2020 - Manufacturing quantity: 999.5 liters. No deviation and observation are associated to this batch. This batch was not concerned by any change control. The results of QC testing are conform at specifications. All parameters verified during manufacturing of</p>
31-Aug-2019	UAE; 19UK002907; -, United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: Home flea treatment; Route: unknown Was the product used ok?: Unknown to Company	N/A	31-Aug-2019	2 Week(s)	D-D	<p>As reported by the animal owner, a dog (signalment otherwise unknown), was treated with FRONTLINE PLUS SPOT ON DOG (estimated as FRONTLINE PLUS SPOT ON DOG M) batch number and expiry date unknown, route and frequency unknown, administered by the dog's owner on approximately 17 AUG 2019, as flea treatment. Two weeks later on 31 AUG 2019 the owner reported that the number of fleas had rapidly increased and that it was much worse, the product did not seem to be doing anything, even after thoroughly cleaning and treating the home.</p>
31-Aug-2019	UAE; 19UK002908; -, United Kingdom	Species: Canine Breed: Canine (unknown) Sex: F Sex qualifier: Unknown Age: - Weight: 13 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	31-Jul-2019	31-Jul-2019*	N/A	D-D	<p>As reported by the animal owner, a female dog, weighing 13 lbs (signalment otherwise unknown), was treated with FRONTLINE PLUS SPOT ON DOG (estimated as FRONTLINE PLUS SPOT ON DOG S) batch number and expiry date unknown, 1 pipette, route unknown, administered by the dog's owner on 31 JUL 2019 and again on 28 AUG 2019, as flea treatment. On 31 AUG 2019 the owner reported that the dog was treated on 28 AUG because the dog was crawling again, they had treated the home and had tried everything they possibly could but they did not believe the first treatment killed them in the beginning.</p>
02-Sep-2019	UAE; 19UK002909; -, United Kingdom	Species: Feline Breed: Feline (unknown) Sex: F Sex qualifier: Neutered Age: 6.00 Year(s) Weight: 5.5 kg	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	N/A	10-Aug-2019	2 Day(s)	D-D	<p>Skin inflamed and itchy, scabbed over (we assume application site) less than 2 days after product application. Reaction duration 10 days approx.</p>
31-Aug-2019	UAE; 19UK002914; -, United Kingdom	Species: Feline Breed: Feline (unknown) Sex: F Sex qualifier:	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other	N/A	2019*	N/A	D-D	<p>As reported by the animal owner, a female feline (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON CAT, batch and expiry unknown, dose details unknown) for an unknown indication. The animal owner reports that it was a waste of money. The animal is still wriggled</p>

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
 Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
 *indicates Approximate date or weight

Page 257 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).
 Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.
 Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00264

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Unknown Age: - Weight: Unknown				products Route: unknown Was the product used ok?: Unknown to Company					with fleas. According to the instructions the animal can't be treated again for 4 weeks and so she is going to suffer while the fleas multiply. The animal owner wishes that they had gone to the vet and state that they can't stand to see the animal suffer for 4 weeks. Start date added for submission purposes only.
01-Sep-2019	UAE; 19UK002915; -; United Kingdom	Species: Canine Breed: German Shepherd Dog Sex: M Sex qualifier: Unknown Age: 10.00 Year(s) Weight: 45 kg	2	2	0	Product used: FIPRONIL SPOT ON DOG Other products used: FRONTLINE PETCARE HOME AND ENVIRONMENT FLEA SPRAY; Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	N/A	18-Aug-2019	N/A	D-D	As reported by the animal owner, Ben, a 10 year old German Shepherd cross Mastiff canine, weighing 45 kg, and one other canine (signalment otherwise unknown) were administered FRONTLINE SPOT ON DOG XL (batch R60905AR and expiry MAR 2020, further details unknown) topically to the back of the neck, by the animal owner, for several years to control fleas. The animal owner also used FRONTLINE PETCARE HOMEGARD HOUSEHOLD FLEA SPRAY (batch 9181-500A expiry APR 2021). After the last application on 18 AUG 2019, both the animal owner's dogs had got fleas. The animal owner has taken their dogs to the vets as the fleas had not cleared. The vet prescribed another flea medication which has eradicated the fleas. Their vet also suggested that they contact the MAH to let them know that the FRONTLINE they used did not kill the fleas. The animal owner added that they use the product every 6 weeks in the summer and also in the winter at an unknown interval. The last four dates that the animal owner applied the product were 19 AUG 2019, 07 JUL 2019, 02 JUN 2019 and 07 APR 2019. No one in the home is being bitten, the animals spend time indoors and outdoors and all animals that live in the household and in contact animals have been treated with a flea product. The animal owner is seeing occasional fleas - less than 5 at the same time - the animals are never bathed or go swimming and the animal owner has treated the home with an environmental flea treatment (FRONTLINE PETCARE HOMEGARD HOUSEHOLD FLEA SPRAY), washed the pet's bedding at over 60 degrees and regularly vacuumed all areas that the pets can access. On 24 SEP 2019 the animal owner added that they do not agree that the animal is picking up hitchhiker fleas as after their dog was treated at the vets the fleas disappeared within 48 hours. The product used by the vet was NEXGARD SPECTRA.
01-Sep-2019	UAE; 19UK002916; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: No (Overdose)	N/A	2019*	N/A	D-D	As reported by the animal owner, a male canine (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON DOG M) (batch 3661103003441 expiry unknown) (details unknown) by the animal owner at a dose of 3 doses in three weeks, for fleas. The animal owner wonders if there is a faulty batch of FRONTLINE as they have used 3 vials in 3 weeks and it hasn't cleared up their dog's fleas, which he got out on a walk. They have used three months worth and still got fleas and shouldn't have used three months worth in 3 weeks. Start date added for submission purposes only.
01-Sep-2019	UAE; 19UK002917; -; United Kingdom	Species: Canine Breed: Terrier Breeds (500 Series) Sex: M Sex qualifier: Unknown Age: 3.00 Year(s)	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON;	N/A	11-Aug-2019	0 Day(s)	D-D	As reported by the animal owner, Reg, a 3 year old male Terrier canine weighing 11 kg (signalment otherwise unknown) was administered FRONTLINE SPOT ON DOG M (batch R21806AX and expiry NOV 2020) topically to the area under the collar on top of the neck, monthly by the animal owner on 21 AUG 2019 for fleas. The animal has been on FRONTLINE for many years. Three weeks ago (11 AUG 2019) the animal owner noticed that the animal had an infestation of fleas or lice. The animal owner gave

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 258 of 867

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

v1.2

ED_005739D_00014390-00265

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: 11 kg				Route: Topical / Cutaneous Was the product used ok?: Unknown to Company					the animal an extra dose of FRONTLINE but this made no difference. The animal owner continued to find live fleas on the animal every day for the next fortnight, until they used Credelio which has done the job. The animal owner added that they usually use FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG M) (batch and expiry unknown) and that the last three dates that they applied the product were 27 JUL 2019, 29 JUN 2019 and 02 JUN 2019. The animal uses the product all year round and noticed fleas on the animal on 20 AUG 2019. The animal owner reports that no one in the home is being bitten but they have had some insect bites over the summer and these could be from midges/mosquitoes - it is impossible to tell. The animal spends time indoors and outdoors and in a second indoor environment. All animals in the household and in contact animals have been treated, the animal owner is seeing many fleas (more than 5 at the same time) and the animal is bathed or goes swimming more than once a week in rivers/ponds. The animal owner has washed the pets bedding at over 60 degrees and regularly vacuumed all areas that the pet can access. The animal owner adds that after applying FRONTLINE on 21 AUG 2019, they combed through the animal's coat every evening for 6 days and found 4 to 7 living fleas on the animal every time (which they removed and crushed). After that they went to the vets and bought a stronger product (Credelio). They continued combing he animal and found no living insects on him
01-Sep-2019	UAE; 19UK002918; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, two canines (signalment otherwise unknown) were administered FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG M) (batch and expiry unknown) (details unknown) by the animal owner for fleas. The animal owner reports that they normally treat their animals with Advantage but recently they noticed that it wasn't working as well as it was, and so they changed to FRONTLINE PLUS as they had heard that it was really good. Unfortunately not only has it not worked and their pets are running alive with fleas, it is now going to cost the animal owner to buy more fleas treatments for all of them and also they have to get their house fumigated. They feel that the advertisement of the product is very misleading and are disappointed and angered at the result of a product that has been advertised as such a great treatment. The animal owner also has 3 cats that are reported in the linked case. Start date added for submission purposes only.
01-Sep-2019	UAE; 19UK002919; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	3	3	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, three felines (signalment otherwise unknown) were administered FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON CAT) (batch and expiry unknown) (details unknown) by the animal owner for fleas. The animal owner reports that they normally treat their animals with Advantage but recently they noticed that it wasn't working as well as it was, and so they changed to FRONTLINE PLUS as they had heard that it was really good. Unfortunately not only has it not worked and their pets are running alive with fleas, it is now going to cost the animal owner to buy more fleas treatments for all of them and also they have to get their house fumigated. They feel that the advertisement of the product is very misleading and are disappointed and angered at the result of a product that has been advertised as such a great treatment. The animal owner also has 2 dogs that are reported in the linked case. Start date added for submission purposes only.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 259 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00266

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
02-Sep-2019	UAE; 19UK002920; -, United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	4	4	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	Jun-2019*	N/A	D-D	As reported by the animal owner, four canines (signalment otherwise unknown) were administered FRONTLINE (assumed FRONTLINE SPOT ON DOG M) (batch and expiry unknown) (details unknown) by the animal owner for a flea infestation. The animal owner has religiously used FRONTLINE on their dogs for years with fantastic results every time. However this year the animal owner has had a flea infestation for the past 3 and a half months. They have used FRONTLINE three times in this period and still they have fleas. The animal owner owns four dogs and a cat, which has also been treated three times. The house has been treated twice as well. The animal owner is also a dog groomer and does this from their house. They are really disappointed as it seems not to be doing the job. Over the past 3 months they have spent three hundred pounds on products that are not working. UPDATE: 27 SEP 2019: QA results received. Investigation completed for FIPRONIL SPOT ON DOG Lot Unknown, expiry. Case investigated by France - Toulouse. Final complaint evaluation :An adverse event for Frontline Dog, batch unknown, was received by BIAH QA on the 11 September 2019. Recurrence : This is the 6th complaints received for a LOE, in the past 12 months, all batches included of Frontline Dog. The sample complaint is not received and requested. No pictures are attached for this case. This defect is rare, it represents 0.2 ppm of every batch produced in 2017 (17 complaints for 78 447 597 pipettes) (including all batches of Frontline Regular and Combo for Cats and Dogs/all ranges). Stability : the tests of stability are conform at the specifications. Quality issue : at this day, no knowledge of any known quality problem on the product. All batches produced are examined and deviation investigated, a release decision is taken among batch records review and quality control results. All released batches are conform with GMP and Marketing Authorization file. No impact for the quality of product and no impact for
31-Aug-2019	UAE; 19UK002921; -, United Kingdom	Species: Feline Breed: Feline (unknown) Sex: F Sex qualifier: Unknown Age: 8.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: FRONTLINE PETCARE HOME AND ENVIRONMENT FLEA SPRAY; Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	20-Aug-2019	20-Aug-2019	0 Day(s)	D-D	As reported by the animal owner, Charlie, an 8 year old female feline (signalment otherwise unknown) was administered FRONTLINE PLUS SPOT ON CAT (batch S41113AW expiry AUG 2021) topically to the nape of the neck, by the animal owner, at a dose of 1 dose on 20 AUG 2019 for fleas. The animal owner reports that they bought the 6 vial pack for their cat however has discovered that the product they sent failed several of the Genuine Authenticity checks including the QR code being unrecognised, the measurements are in metric whereas they should be in fluid ounces, the genuine product does not have a use by date and the inner packaging is quite square whereas the genuine product should have a separating cut out between each vial. Finally the product has had no effect whatsoever on the animal treated. The animal owner adds that they first noticed fleas on the animal prior to purchasing the product, people in the home are being bitten and that the animal spends time both indoors and outdoors. The animal owner is seeing occasional fleas - less than 5 at the same time, the animal never bathes or goes swimming and the animal owner has treated the house with FRONTLINE PETCARE HOMEGARD HOUSEHOLD FLEA SPRAY (batch and expiry unknown), washed all the pet's bedding at over 60 degrees, regularly vacuumed all areas that the pet can access and steam cleaned the skirting boards and flooring. QA results received: The complaint description is lack efficacy and

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 260 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00267

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											<p>suspected counterfeit.</p> <p>The retention sample is conform (aspect). Batch record investigation Bulk batch: S411</p> <p>Manufacturing date: 11/09/2018 - Expiry date: 08/2021 - Manufacturing quantity: 999.5 liters</p> <p>No deviation associated to this batch and one observation not associated to this defect</p> <p>This batch was not concerned by any change control. The results of QC testing are conform at specifications. All parameters verified during manufacturing of this batch of bulk are conform.</p> <p>Filling batch: S41113, Manufacturing date:</p>
02-Sep-2019	UAE; 19UK002922; -, United Kingdom	Species: Feline Breed: Feline (unknown) Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: No (Overdose)	N/A	2019*	N/A	D-D	<p>As reported by the animal owner, a male feline (signalment otherwise unknown) was administered FRONTLINE DUO (assumed FRONTLINE PLUS SPOT ON CAT) (batch and expiry unknown) (details unknown) at a dose of 2 doses in three weeks, for fleas. The animal owner reports that they are still finding fleas on this animal and they are wondering if they have a rubbish box. They have ordered more to see if that is the case and wants to know that it will be safe for their animal. Start date added for submission purposes only.</p> <p>UPDATE 26 SEP 2019: QA results received. Investigation completed for FIPRONIL 10%/S METHOPRENE 12% SPOT ON Lot Unknown, expiry . Case investigated by France - Toulouse.</p> <p>Final complaint evaluation: An adverse event for FRONTLINE PLUS SPOT ON CATS, batch unknown, was received by BIAH QA on the 11th of September 2019. This is the 31st complaint received for this LOE, in the past 12 months, all batches of Frontline Cat. This defect is rare, it represents 0.2 ppm of every batch produced in 2017 (17 complaints for 78 447 597 pipettes) (including all batches of Frontline Regular and Combo for Cats and Dogs/all ranges). The complaint sample is not received and pictures are not attached to this case. Batch record investigation: Batch unknown.</p> <p>Root cause investigation: Stability : during the test of stability, we can observe that one batch out of thirteen an increase in the water content (regular cat). Efficacy, safety and quality of the product not in question because the whole dose is applied. The tests of stability are conform at the specifications. Quality issue : at this day, no knowledge of any known quality problem on the product.</p> <p>All batches produced are examined and deviation investigated, a release decision is taken among batch records review and quality control results. All released batches are conform with GMP and Marketing Authorization file.</p> <p>Conclusion: All batches produced are examined and deviation investigated, a release decision is taken among</p>
02-Sep-2019	UAE; 19UK002923; -, United Kingdom	Species: Feline Breed: Feline (unknown) Sex: M Sex qualifier: Unknown Age: 15.00 Year(s) Weight: 4 kg*	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used	Mar-2019*	29-Aug-2019	N/A	D-D	<p>As reported by the animal owner, Punch, a 15 year old male feline weighing approximately 4 kg (signalment otherwise unknown) was administered FRONTLINE PLUS SPOT ON CAT (batch and expiry unknown) (details unknown) to the back of the neck in the evening, monthly for just under six months (estimated to start MAR 2019) for fleas. The animal owner asks if the product is no longer effective on cats and if they become resilient to it. They have been using the product for just under 6 months and they used the last treatment before going on a 2 week holiday. On their return the animal has a massive infestation of fleas and they are not sure what they can use as the last treatment was done under 3 weeks ago. The animal owner first noticed fleas on their pet on 29 AUG 2019. The animal owner adds that they treat the animal monthly all year round</p>

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 261 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

v1.2

ED_005739D_00014390-00268

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						ok?: Unknown to Company					and that the last four dates that they applied the product were 11 AUG 2019, 14 JUL 2019, 09 JUN 2019 and 12 MAY 2019 and they have a regular schedule. People in the home are being bitten and the animal spends time indoors and outdoors. The animal owner is seeing many fleas - more than 5 at the same time, the animal never goes swimming or is bathed and the animal owner has both treated the home with an environmental flea treatment and regularly vacuumed all areas that the pet can access. On 16 SEP 2019 the animal owner reported that they treated the cat with FRONTLINE PLUS and used spray on their house as instructed. They can confirm that their cat still has live fleas moving on him and fresh eggs in his fur.
01-Sep-2019	UAE; 19UK002927; -; United Kingdom	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: M Sex qualifier: Unknown Age: 11.00 Year(s) Weight: 4.7 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	12-Jul-2017	30-Jul-2019	N/A	D-D	As reported by the animal owner, Valentino, an 11 year old male Domestic Short Hair feline weighing 4.7 kg (signalment otherwise unknown) was administered FRONTLINE PLUS SPOT ON CAT (batch and expiry unknown) topically to the base of the neck, by the animal owner, at a dose of 1 dose every 30 days, since 12 JUL 2017 for fleas. The animal owner reports that they have been using FRONTLINE on their cat for years, however their cat became infested with fleas due to a delivery of FRONTLINE mishap. As a result the animal owner had their house fumigated by a pest control specialist and continued using FRONTLINE. However, one month later the animal owner is still finding live fleas on their animal when they comb him with a flea comb. The animal owner submerges them into boiling water in the comb to kill them but they are not sure that FRONTLINE is working on the animal. They are not seeing the fleas in the house so they hope that is a positive sign. The animal owner adds that the animal does go outdoors daily. The animal owner reports that a mishap with the delivery of July's treatment caused the cat to become infested with fleas, which they realised around the middle of JUL 2019 (later added 30 JUL 2019). The animal owner had the whole house fumigated by a pest control specialist and continued to use FRONTLINE, the last application of which would have been the 04 AUG 2019. The animal owner reports that they try not to let the animal out right after application if it is raining, the animal spends time indoors and outdoors and all animals that live in the household or in contact animals have been treated with a flea product. The animal owner is seeing occasional fleas - less than 5 at the same time, the animal never goes swimming or is bathed and the animal owner has treated the house with an environmental flea treatment, washed the pets bedding at over 60 degrees and regularly vacuumed all areas that the pet can access.
02-Sep-2019	UAE; 19UK002936; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	29-Jul-2019*	29-Jul-2019	N/A	D-D	As reported by the animal owner, two large canines (signalment otherwise unknown) were administered FRONTLINE (assumed FRONTLINE SPOT ON DOG L, batch and expiry unknown) by the animal owner five weeks ago (29 JUL 2019) for an unknown indication. The animal owner reports that they purchased FRONTLINE to treat their two large dogs five weeks ago. They immediately applied the drops as per the instructions and proceeded to wash all dog beds, soft furnishings and vacuumed or steam cleaned thoroughly everything else throughout. There are no rugs or carpets in the areas that the dogs have access to. After a week both dogs were still scratching and even more infested with fleas. They don't have contact with other dogs or cats. After seeking advice three weeks later, the animal owner reapplied the drops and thoroughly cleaned the house again. That was a week

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 262 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00269

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											ago(estimated as 26 AUG 2019) and both dogs are still infested, scratching to the point that they are making the skin sore.
02-Sep-2019	UAE; 19UK002937; West Sussex; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: X Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	May-2019*	30-Aug-2019	N/A	D-D	As reported by the animal owner, two felines - one male, one female (signalment otherwise unknown) were administered FRONTLINE SPOT ON CAT (batch S21509AX expiry SEP 2021) topically to the back of the neck, by the animal owner at a dose of 1 dose from MAY 2019 after they saw fleas. The animal owner reports they have two cats and they used the last pipette on Friday (30 AUG 2019). The animal owner put a comb through the cats today (02 SEPT 2019) and found fleas. The animal owner knows how to use the product - part the fur and apply the liquid to the skin and then you comb through the coat to get the dead ones out. The animal owner states that the black cat you cant see the fleas in her fur as she is black, the other cat is black and white and you can see fleas on his face. The animal owner adds that there were a few months when they didn't use the product. They got the cats in NOV 2018 and didn't use anything over the winter months as the fleas don't breed.
03-Sep-2019	UAE; 19UK002942; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a feline (signalment otherwise unknown) was administered FRONTLINE PLUS SPOT ON CAT (batch and expiry unknown) (details unknown) three times by the animal owner for an unknown indication. The animal owner reports that they recently treated their cat three times with FRONTLINE PLUS as directed, but there are still fleas present. The house has also been treated. The animal owner has used FRONTLINE with success in the past but this most recent pack has had no effect . Start date added for submission purposes only. QA results received. This is the 32th complaint received for this LOE, in the past 12 months, all batches of Frontline Cat. This defect is rare, it represents 0.2 ppm of every batch produced in 2017 (17 complaints for 78 447 597 pipettes) (including all batches of Frontline Regular and Combo for Cats and Dogs/all ranges). Stability : during the test of stability, we can observe that one batch out of thirteen an increase in the water content (regular cat). Efficacy, safety and quality of the product not in question because the whole dose is applied. The tests of stability are conform at the specifications. Quality issue : at this day, no knowledge of any known quality problem on the product. All batches produced are examined and deviation investigated, a release decision is taken among batch records review and quality control results. All released batches are conform with GMP and Marketing Authorization file. Conclusion: All batches produced are examined and deviation investigated, a release decision is taken among batch records review and quality control results. All released batches are conform with GMP and Marketing Authorization file. This complaint is categorized as major without impact on the market. This complaint is not justified.
03-Sep-2019	UAE; 19UK002943; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: X Sex qualifier: Mixed Age: 1.00 Year(s) Weight: Unknown	3	3	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products	22-Aug-2019	22-Aug-2019	N/A	D-D	As reported by the animal owner, Sam a 14 year old male neutered, Timmy a 4 year old male neutered and Nala a 1 year old female intact, all felines, were administered FRONTLINE PLUS SPOT ON CAT (batch and expiry unknown) topically to an unknown site, by the animal owner, at a dose of 1 dose, three weeks ago on 22 AUG 2019 as they saw fleas. The animal owner reports that they are still seeing a lot of fleas on all three cats, and a lot of flea dirt. The animals are itching a lot and the product

N/A signifies the information for this field is either not available or not applicable

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Report printed on 25-Oct-2019 at 8:39:59PM

Page 263 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00270

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Route: Topical / Cutaneous Was the product used ok?: Yes					doesn't seem to be working. The animals are inside cats and so do not go outside. The animal owner thinks that the pet sitter has brought the fleas in while they have been on holiday. The animal owner is not being bitten, but they are seeing several fleas on each cat. The animal owner is treating the home with a spray and is already hoovering and washing bedding etc.
03-Sep-2019	UAE; 19UK002944; Cornwall; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	03-Sep-2019*	N/A	D-D	As reported by the animal owner, a large canine (signalment otherwise unknown) was administered FRONTLINE SPOT ON DOG L (batch and expiry unknown, details unknown) for an unknown indication. The animal owner reported that they are very proactive with keeping their animals in top health and keep their flea and worm treatment up to date. They also have their dogs professionally groomed and so know that they were clear of fleas. The animal owner applied the FRONTLINE in line with the instructions and has found a few days later that there were fleas on the animals. They are not happy that the treatment has not worked. The animal owner also used flea treatment for the home as part of their spring clean. The animal owner is not happy and has the remaining treatments left in the original packaging. They have no faith in the product working as they used it impeccably and it clearly didn't work. Subsequently the animal owner has returned to their local vet and had to buy further treatment now prescribed by the vet at an extra cost. Start date added for submission purposes only. This case is linked to 19UK002945 and 19UK002946 as the owner also treated their small dog and cat.
03-Sep-2019	UAE; 19UK002945; Cornwall; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a small canine (signalment otherwise unknown) was administered FRONTLINE SPOT ON DOG S (batch and expiry unknown, details unknown) for an unknown indication. The animal owner reported that they are very proactive with keeping their animals in top health and keep their flea and worm treatment up to date. They also have their dogs professionally groomed and so know that they were clear of fleas. The animal owner applied the FRONTLINE in line with the instructions and has found a few days later that there were fleas on the animals. They are not happy as the treatment has not worked. The animal owner also used flea treatment for the home as part of their spring clean so know that the house is not a hotbed for fleas so to speak. The animal owner is not happy and has the remaining treatments left in the original packaging. They have no faith in the product working as they used it impeccably and it clearly didn't work. Subsequently the animal owner has returned to their local vet and had to buy further treatment now prescribed by the vet at an extra cost. Start date added for submission purposes only. This case is linked to 19UK002944 and 19UK002946.
03-Sep-2019	UAE; 19UK002946; Cornwall; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a feline (signalment otherwise unknown) was administered FRONTLINE SPOT ON CAT (batch and expiry unknown, details unknown) for an unknown indication. The animal owner reported that they are very proactive with keeping their animals in top health and keep their flea and worm treatment up to date. They also have their dogs professionally groomed and so know that they were clear of fleas. The animal owner applied the FRONTLINE in line with the instructions and has found a few days later that there were fleas on the animals. They are not happy that the treatment has not worked. The animal owner also used flea treatment for the home as part of their spring clean so know that the house is not a hotbed for fleas so to speak.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 264 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00271

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											The animal owner is not happy and has the remaining treatments left in the original packaging. They have no faith in the product working as they used it impeccably and it clearly didn't work. Subsequently the animal owner has returned to their local vet and had to buy further treatment now prescribed by the vet at an extra cost. Start date added for submission purposes only. This case is linked to 19UK002944.
03-Sep-2019	UAE; 19UK002948; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	Jul-2019*	Jul-2019*	N/A	D-D	As reported by the animal owner, a canine (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON DOG M, batch and expiry unknown, details unknown) for the last two months (estimated start date JUL 2019) for an unknown indication. The animal owner reports that it has not worked and it has left them with an infestation.
03-Sep-2019	UAE; 19UK002949; Halifax; United Kingdom	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: M Sex qualifier: Neutered Age: 16.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Overdose)	N/A	2019*	N/A	D-D	As reported by the animal owner, Rusty, a 16 year old male neutered Domestic Short Hair feline, of unknown weight and in good condition, was administered FRONTLINE PLUS SPOT ON CAT (batch S41303AW, expiry OCT 2021) topically to an unknown site, by the animal owner at a dose of 3 doses in a month for an unknown indication. The animal owner reports that they are still seeing fleas and have used all three pipettes in a month. They are being bitten at home, have wooden floors and have vacuumed and washed the bedding. The animal has been left outside. Start date added for submission purposes only.
03-Sep-2019	UAE; 19UK002950; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a canine (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON DOG M, batch and expiry unknown, details unknown) for an unknown indication. The animal owner reports that they recently bought FRONTLINE for their dog and it had no effect whatsoever. Start date added for submission purposes only.
03-Sep-2019	UAE; 19UK002951; -; United Kingdom	Species: Canine Breed: Poodle (Miniature) Sex: M Sex qualifier: Unknown Age: 4.00 Year(s) Weight: 7.5 - 10 kg	2	2	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	N/A	11-Aug-2019	0 Day(s)	D-D	As reported by the animal owner, Bailey and Alfie, two male Poodle cross canines, Bailey aged 10 years and weighing 10 kg, and Alfie aged 4 years and weighing 7.5 kg (signalment otherwise unknown) were administered FRONTLINE SPOT ON DOG S (batch number S21209AW expiry unknown AUG 2021) on 11 AUG 2019 by the animal owner topically between the shoulder blades for an unknown indication. The animal owner reports that they have read online that FRONTLINE is not so effective for the prevention of fleas and that some dogs have an immunity against this. The treated their two dogs with the product on 11 AUG 2019 and they have both since developed a flea infestation. The animal owner has purchased sufficient to treat their two dogs for 12 months and

N/A signifies the information for this field is either not available or not applicable

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

Report printed on 25-Oct-2019 at 8:39:59PM

*indicates Approximate date or weight

Page 265 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00272

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											they are very disappointed with this development. The product is applied every two months, they use the product all year round, they started using the product for their current flea issue on 04 SEP 2019, having noticed fleas on 03 SEP 2019. The last four dates they applied the product to the animals were 16 FEB 2019, 16 APR 2019, 15 JUN 2019 and 11 AUG 2019. People in the home are not being bitten, the pets spend time indoors, outdoors and in a second environment, all animals in the home have been treated with a flea product, the animal owner has not seen fleas but there is flea dirt and evidence of fleas in the dog's fur, the dogs get bathed approximately every 6 weeks and this is never within 2 days of product application and the animal owner has not lived in the home for less than a year. The home has been treated with an environmental flea spray, the pets' bedding has been washed at over 60 degrees and all areas the pets can access are regularly vacuumed.
03-Sep-2019	UAE; 19UK002953; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: X Sex qualifier: Unknown Age: - Weight: 4 kg*	7	7	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: Indorex Flea Spray; Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	N/A	03-Sep-2019	18 Day(s)	D-D	As reported by the animal owner, Smoggy, Bear, Gypsy, Dude, Havoc, Angel and Teddy, 7 felines, three male and four female weighing over 4 kg (signalment otherwise unknown) were administered FRONTLINE PLUS SPOT ON CAT (batch, expiry and further details unknown) topically to the base of the neck, monthly by the animal owner on 16 AUG 2019 for an unknown indication. The animal owner reports that they treated all their cats, and after flea combing today has found live fleas on all. The animal owner treats them regularly every month, all year round, and flea sprays the house weekly with Indorex flea spray. They do go outside. The animal owner managed to grab two of the fleas but one jumped and they don't know where it went in the kitchen. The animal owner hoovers at least 3 times a day and asks why they are seeing them alive still. The animal owner feels that the treatment is not working for the full length it should be and has an absolute anxiety about fleas and it is causing them much stress. They ask if they need to change to a different brand of treatment as they feel that it is not working and how can they be sure any fleas that come off in the house will die. The last four dates that the animal owner applied the product were 16 AUG 2019, 19 JUL 2019, 22 JUN 2019 and 26 MAY 2019. The animal owner has been bitten. They have washed the pets' bedding and so they do not understand why they are seeing fleas on their cats. They haven't seen any on their two dogs and all are weekly flea combed. The animal owner has seen fleas 2 weeks after treatment, and the animal owner asks why FRONTLINE PLUS is only being effective for the first couple of weeks. They are thinking of changing to a different product as they are not happy that they do everything by the book and pay a lot of money for it not to work.
03-Sep-2019	UAE; 19UK002954; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	01-Sep-2019	N/A	D-D	As reported by the animal owner, Princess a female 4 kg feline, and one other feline (signalment otherwise unknown) were administered FRONTLINE (assumed FRONTLINE SPOT ON CAT) (batch and expiry unknown) (details unknown) by the animal owner for an unknown indication. The animal owner reports that they are reporting 48 hours after their two cats flea treatments. The animal owner had two FRONTLINE PLUS boxes with multiple pipettes and this was their last. Their cat Princess has just had three kittens. Both cats have been defleaded and are indoor cats and the animal owner also defleaded the house, but after their last treatment has been given there are fleas. The vets gave flea treatment to the kittens as a precaution, but the animal owner has

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 266 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

v1.2

ED_005739D_00014390-00273

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											thrown out all the packaging as they trusted FRONTLINE. The animal owner is fuming as they deflea and worm precautionally. Now the animal owner has to deflea 1 week old kittens, 2 cats and the house because the product failed for whatever reason, when it never has before. The animal owner is now out of pocket for their furbabies which is upsetting as they are going to get itchy.
01-Sep-2019	UAE; 19UK002956; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a canine (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON DOG M) (batch and expiry unknown) (details unknown) by the animal owner for an unknown indication. The animal owner reports that they price that they paid was terrible for it does not work. They applied the product as instructed and the thought that it would do the job, but it didn't. Their dog still had fleas 4 days later. Start date added for submission purposes only.
04-Sep-2019	UAE; 19UK002960; County Durham; United Kingdom	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: F Sex qualifier: Neutered Age: 5.00 Year(s) Weight: 4 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	02-Sep-2019	02-Sep-2019	N/A	D-D	As reported by the animal owner, Zena, a 5 year old female neutered Domestic Short Hair feline, weighing 4 kg and in good condition, was administered FRONTLINE PLUS SPOT ON CAT (batch S41113 expiry AUG 2021) topically to an unknown site, by the animal owner, at a dose of 1 pipette, on 02 SEP 2019 for an unknown indication. The animal owner reports that this is the first time that the animal has been treated this year. They noticed fleas on Monday (02 SEP 2019) and have been bitten as well.
04-Sep-2019	UAE; 19UK002961; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, approximately two felines (signalment otherwise unknown) were administered FRONTLINE PLUS SPOT ON CAT (batch, expiry and further details unknown) for an unknown indication. The animal owner reports that they bought the product for their cats and it has had no effect. They are still constantly scratching and they are still finding live fleas on them. The animal owner has always used FRONTLINE before absolutely no problem and fleas have cleared no problem. Start date added for submission purposes only.
04-Sep-2019	UAE; 19UK002962; -; United Kingdom	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: M Sex qualifier: Neutered Age: 6.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the	05-Aug-2019	19-Aug-2019	2 Week(s)	D-D	As reported by the animal owner, KitKat a 6 year old neutered male Domestic Shorthair feline, of unknown weight and in unknown condition was treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), 1 pipette used, on the back of the neck, administered by the cat's owner on 05 AUG 2019. The owner saw fleas a couple of weeks after applying the treatment (date estimated as 19 AUG 2019) and so went to the vets who advised the owner that FRONTLINE did not work and did not kill the fleas. The vet gave the owner something else, which had worked. The owner had also treated the house (product unknown). The owner had not used any product prior to the

N/A signifies the information for this field is either not available or not applicable

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

Report printed on 25-Oct-2019 at 8:39:59PM

*indicates Approximate date or weight

Page 267 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00274

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						product used ok?: Yes					FRONTLINE, but ages ago got something from the vet which killed the fleas instantly.
04-Sep-2019	UAE; 19UK002963; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-C	As reported by the animal owner, a male dog was treated with FRONTLINE PLUS (estimated as FRONTLINE PLUS SPOT ON DOG M), and it ended up making their dog scratch himself so much he had blood all across his shoulder and they had to take him to the vets. The dog's skin was horrendous when the vet shaved off where the affected area was to be. Start date of event added for submission purposes only.
04-Sep-2019	UAE; 19UK002966; -; United Kingdom	Species: Feline Breed: Feline various breeds Sex: F Sex qualifier: Neutered Age: 1.00 Year(s) Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	N/A	31-Aug-2019	N/A	D-D	As reported by the animal owner via Social Media, Molly, a 6 year old female neutered Domestic Shorthair cat, and Milly, a 1 year old female neutered tortoiseshell cat of unknown breed, were administered FRONTLINE PLUS SPOT ON CAT (batch and expiry unknown) topically to the back of the neck, by the animal owner at a dose of 1 dose every 4 weeks, last applied 4 days ago (31 AUG 2019) for an unknown indication. The animal owner reports that they still have fleas. The fleas are biting the animal owner and their daughter since they put the FRONTLINE on them. The animal owner has been using FRONTLINE for years. The animal owner's daughter has an Autism Spectrum Disorder and is freaking out about the fleas, obsessing about them and won't sleep because she is worried that they are biting her. The animal owner sees dead fleas by the window where the cats sleep, and when they put a comb through the fur they see live ones. The animal owner puts them in fairy liquid to kill them because they can swim out of just water. Both the animals are very itchy, especially the Tortie (Tortoiseshell). The animal owner is vacuuming and washing bedding and has used a home spray (product unknown). There is a stray cat that comes into the garden that the Tortie is very fond of. The animal owner added that the product should have worked by now and they cost a lot of money. The product is the same one that they have used since the 6 year old cat was 1 year old. Neither animal has medication nor medical conditions.
04-Sep-2019	UAE; 19UK002969; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	3	3	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	27-Aug-2019	N/A	D-D	As reported by the animal owner, three felines (signalment otherwise unknown) were administered FRONTLINE (assumed FRONTLINE SPOT ON CAT, batch and expiry unknown, details unknown) by the animal owner on 27 AUG 2019 for an unknown indication. The animal owner reports that they still have them (fleas) which they are not happy about.
04-Sep-2019	UAE; 19UK002970; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: M Sex qualifier:	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other	N/A	14-Aug-2019*	N/A	D-D	As reported by the animal owner, a male feline (signalment otherwise unknown) was administered FRONTLINE SPOT ON CAT (batch unknown, expiry SEP 2021, details unknown) for an unknown indication. The animal owner reported that they purchased the product three weeks ago to treat their cat. They

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 268 of 867

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00275

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Unknown Age: - Weight: Unknown				products Route: unknown Was the product used ok?: Unknown to Company					have always used FRONTLINE and it has been working fine, however this batch has not worked. It did not get rid of his fleas and the animal owner had to remove a tick from the animal only one week after application. The animal owner regularly treats their house as well so this result is very disappointing. The animal owner asks if there have been problems from other people and if the product has been weakened. The animal owner reports that they will now have to take their animal to the vet to get stronger treatment before he infects the house. Start date added for submission purposes only.
04-Sep-2019	UAE; 19UK002971; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a feline (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON CAT, batch and expiry unknown, details unknown) for fleas. The animal owner reports that they bought this flea treatment and it hasn't worked. They have used flea spray in the house, hoovered regularly and washed the bedding etc and are really disappointed with the product. Start date added for submission purposes only.
05-Sep-2019	UAE; 19UK002974; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, two felines (signalment otherwise unknown) were administered FRONTLINE (assumed FRONTLINE SPOT ON CAT, batch and expiry unknown, details unknown) for an unknown indication. The animal owner reports that they recently bought FRONTLINE for their two cats. It has not killed the fleas. They used a second treatment 3 weeks later and it still has not worked. It was a total waste of money. Start date added for submission purposes only.
05-Sep-2019	UAE; 19UK002977; -; United Kingdom	Species: Feline Breed: Russian Blue Sex: F Sex qualifier: Neutered Age: 3.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	N/A	2019*	N/A	D-D	As reported by the animal owner, Pebbles a 3 year old female neutered Russian Blue feline, of unknown weight and in good condition, was administered FRONTLINE PLUS SPOT ON CAT (batch S41113AW expiry FEB 2021) topically to an unknown site, by the animal owner at a dose of 1 dose monthly from an unknown date for an unknown indication. The animal owner reports that they are still seeing fleas and that the product doesn't work. They are biting the animal owner and they pick the fleas off and drown them. Start date added for submission purposes only.
05-Sep-2019	UAE; 19UK002981; -; United Kingdom	Species: Canine Breed: Chihuahua Sex: M Sex qualifier: Neutered Age: 7.00 Year(s) Weight: 8.2 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	Dec-2018*	May-2019*	N/A	D-D	As reported by the animal owner, Rupert, a 7 year old male neutered Chihuahua cross canine, weighing 8.2 kg and in good condition, was administered FRONTLINE SPOT ON DOG S (batch and expiry unknown) topically to an unknown site, by the animal owner monthly for 9 months (start date DEC 2018) for flea treatment. The animal owner was previously using Advocate but switched to FRONTLINE SPOT ON due to the cost of Advocate. They haven't had a problem until 3-4 months ago when the animal got fleas. The animal owner suspects that the fleas were from his girlfriend's cat. The animal owner says that the product isn't

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 269 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00276

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						ok?: Yes					working at all and it is definitely not killing any of the fleas. The animal owner is seeing 10-11 fleas every day on the dog, who is now ripping chunks of his fur out and is distressed. The product is being used correctly, monthly with no gaps. The animal owner claims that the company have made FRONTLINE SPOT ON weaker now since FRONTLINE PLUS has been brought out. The animal owner hasn't been bitten at all within the home, and has treated the house anyway with flea bombs and washing bedding and hoovering etc. The animal owner mentioned that they have moved to a new apartment but it was decontaminated before they moved in. On 27 SEP 2019 QA results were received: Investigation completed for FIPRONIL SPOT ON DOG Lot Unknown, expiry. Case investigated by France - Toulouse. Final complaint evaluation: An adverse event for Frontline Dog, batch unknown, was received by BIAH QA on the 12 September 2019. Recurrence : This is the 7th complaints received for a LOE, in the past 12 months, all batches included of Frontline Dog. The sample complaint is not received and requested. No pictures are attached for this case. This defect is rare, it represents 0.2 ppm of every batch produced in 2017 (17 complaints for 78 447 597 pipettes) (including all batches of Frontline Regular and Combo for Cats and Dogs/all ranges). Stability : the tests of stability are conform at the
05-Sep-2019	UAE; 19UK002982; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a cat (signalment otherwise unknown), was treated with FRONTLINE (assumed to be FRONTLINE SPOT ON CAT) batch number and expiry date unknown, route and frequency unknown, administered by unknown, on an unknown date and the owner reported on 05 SEP 2019 that the product had not worked at all. The owner had bought 3 units of FRONTLINE.
05-Sep-2019	UAE; 19UK002985; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	N/A	05-Sep-2019	5 Day(s)	D-D	As reported by the animal owner, a dog (signalment otherwise unknown), was treated with FRONTLINE PLUS or FRONTLINE SPOT ON DOG (estimated as FRONTLINE PLUS SPOT ON DOG M) batch number and expiry date unknown, administered by the dog's owner every 30 days as recommended, the last dose was administered on 31 AUG 2019. The owner reported on 05 SEP 2019 that they were being bitten and they had a flea infestation. There are also 3 cats in the household - see linked case 19UK002986.
05-Sep-2019	UAE; 19UK002986; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	3	3	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products	N/A	05-Sep-2019	5 Day(s)	D-C	As reported by the animal owner, 3 cats (signalment otherwise unknown), were treated with FRONTLINE PLUS or FRONTLINE SPOT ON CAT (estimated as FRONTLINE PLUS SPOT ON CAT) batch number and expiry date unknown, administered by the cat's owner every 30 days as recommended, the last dose was administered on 31 AUG 2019. One of the cats fell in the water within 1 day of application as the owner lived on a boat. The owner reported on 05 SEP 2019 that they were being bitten and they had a flea infestation. The owner wanted to know if they could apply

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 270 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00277

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Route: Topical / Cutaneous Was the product used ok?: Yes					more product to the cat. Case linked to 19UK002985. This case is classified as both 'SLEE' and 'Adverse Reaction' but due to a limitation of the database it might be that only the highest hierarchical product problem type, which is 'Adverse Reaction', has been transmitted.
05-Sep-2019	UAE; 19UK002993; -; United Kingdom	Species: Feline Breed: Ragdoll Sex: M Sex qualifier: Unknown Age: 2.00 Year(s) Weight: 3 - 5.5 kg	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	11-Jul-2019	Jul-2019*	N/A	D-D	As reported by the animal owner, two male Ragdoll felines; Sid a 2 year old weighing 5.5 kg, and Wallace a 3 year old weighing 3 kg, were administered FRONTLINE PLUS SPOT ON CAT (batch S41113AW and expiry AUG 2021) monthly at an unknown dose, by the animal owner(further details unknown) for an unknown indication. The animal owner reports that they both had two treatments and the animal owner treated the house but they still have fleas on both cats. The animal owner reports that they use the product all year round and that they started using the product for their current flea issue in JUN 2019. They first noticed fleas on the animals in JUN 2019 and the last four dates that the product was applied were 11 JUL 2019, 08 AUG 2019 and 05 SEP 2019. The animal owner uses the product as instructed, people are being bitten in the house and the animals spend time indoors only. All animals in the household and in contact animals have been treated with a flea product, the animal owner is seeing many fleas - more than 5 at the same time - and the animals are never bathed or go swimming. The animal owner has treated the home with an environmental flea treatment (product unknown), washed the pet's bedding at over 60 degrees and regularly vacuumed all areas that the pets can access.
05-Sep-2019	UAE; 19UK002995; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: Household flea spray; Organic flea treatments; Route: unknown Was the product used ok?: Unknown to Company	N/A	10-Aug-2019	N/A	D-C	As reported by the animal owner, a dog (signalment otherwise unknown), was treated with FRONTLINE PLUS SPOT ON DOG L (batch number and expiry date unknown), route and frequency unknown, administered by the dog's owner on 09 AUG 2019. The owner purchased 3 pipettes of FRONTLINE PLUS SPOT ON DOG L from an online pet store on 07 AUG 2019 and first contacted them on 10 AUG 2019 to report that the product was not working. The owner then re-contacted the online store on 16 AUG 2019, 19 AUG 2019 and 20 AUG 2019 requesting a refund, as they felt the product has not done what it was meant to do and they were looking to purchase an alternative product. The owner had reported that the product was not working to kill fleas or stop the eggs from hatching. The owner had also purchased a household flea spray and separate organic flea treatments for the animal, but still insisted that the products did not work, they were still finding live fleas on the pet and finding eggs/pupae around the house. On 04 SEPT 2019 the owner also reported that the dog had experienced and allergic reaction to the product. This case is classified as both 'SLEE' and 'Adverse Reaction' but due to a limitation of the database it might be that only the highest hierarchical product problem type, which is 'Adverse Reaction', has been transmitted.
05-Sep-2019	UAE; 19UK002996; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: Organic flea treatments;	N/A	10-Aug-2019	N/A	D-D	As reported by the animal owner, a cat (signalment otherwise unknown), was treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), route and frequency unknown, administered by the cat's owner on 09 AUG 2019. The owner purchased 6 pipettes of FRONTLINE PLUS SPOT ON CAT from an online pet store on 07 AUG 2019 and first contacted them on 10 AUG 2019 to report that the product was not working. The owner then re-contacted the online store on 16 AUG 2019, 19

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 271 of 867

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00278

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Household flea spray; Route: unknown Was the product used ok?: Unknown to Company					AUG 2019 and 20 AUG 2019 requesting a refund, as they felt the product has not done what it was meant to do and they were looking to purchase an alternative product. The owner had reported that the product was not working to kill fleas or stop the eggs from hatching. The owner had also purchased a household flea spray (product unknown) and separate organic flea treatments for the animal, but still insisted that the products did not work, they were still finding live fleas on the pet and finding eggs/pupae around the house. Case linked to 19UK002995.
06-Sep-2019	UAE; 19UK003000; -; United Kingdom	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: F Sex qualifier: Neutered Age: 13.00 Year(s) Weight: 5 kg*	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON; Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	N/A	26-Jul-2019*	N/A	D-D	As reported by the animal owner, Molly, a 13 year old female neutered Domestic Short Hair feline, weighing approximately 5 kg and in good condition, was administered FRONTLINE (assumed FRONTLINE SPOT ON CAT, details unknown) for an unknown indication. The animal owner reports that they have been using FRONTLINE on their cat for some time. They recently noticed their cat had fleas so they bought FRONTLINE PLUS six weeks ago (approximately 26 JUL 2019) and treated the animal twice within a month, which made no difference at all. The animal owner had to take her to the vets and explained that she had been given two treatments of FRONTLINE PLUS. They vet said to the animal owner that they had stopped using FRONTLINE and had many complaints that it was no longer working. The animal owner adds that this has caused a great deal of stress, time and a waste of money. The animal owner then added that they treated the animal 3 times in six weeks, and that they believe that the product isn't working as they are seeing very active fleas still on the animal (two to three a day). The animal owner says that it is like applying water. The animal owner has been bitten a few times, but only when in contact with the animal. The animal owner's husband isn't being bitten and the animal doesn't come inside very often. The animal is mainly outside and sleeps in the garage. The carpets and floors in the house are being redone and so the animal owner does not believe that there is a problem within the home as nobody else is being bitten, only the animal owner when they touch the cat. The animal owner has washed the bedding and treated the garage too. The animal owner is hoovering all areas to be safe. The vet has moved the animal owner onto a different flea treatment (Advocate). The animal owner does not want to use FRONTLINE any more.
06-Sep-2019	UAE; 19UK003001; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: Advocate; Route: unknown Was the product used ok?: Unknown to Company	Jul-2019*	06-Sep-2019	N/A	D-D	As reported by the animal owner, 2 cat's (signalment otherwise unknown), were treated with FRONTLINE PLUS SPOT ON CATS (batch number and expiry date unknown), route and frequency unknown, administered by the cat's owner for the past 2 months (application dates estimated as JUL 2019 and AUG 2019), instead of Advocate. On 06 SEP 2019 the owner reported that when they combed both cats they found a dozen fleas on the largest cat and a few on the other cat. The product was not working. The owner was picking up a new puppy on the 07 SEP 2019 and thought that the puppy would be immediately at risk.
06-Sep-2019	UAE; 19UK003007; -; United Kingdom	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: M	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON	Aug-2019*	Aug-2019*	N/A	D-D	As reported by the animal owner, Sammy, a 6 year old male neutered Domestic Short Hair feline, of unknown weight and condition, was administered FRONTLINE PLUS SPOT ON CAT (batch S41113AW expiry AUG 2021) topically to the back of the neck, by the animal owner, at a dose of 1 pipette a month ago

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 272 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00279

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: Neutered Age: 6.00 Year(s) Weight: Unknown				Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)					(estimated AUG 2019) as the animal had fleas. The animal owner treated the animal and noticed even more fleas on him. They treated him again 10 to 14 days later and is appalled at the amount of fleas that are still on the animal. They should all be gone. The animal owner went to the vets recently and they gave something else, which has worked and all the fleas have gone. The animal owner hasn't used a flea product prior to the first FRONTLINE as the animal doesn't get fleas.
06-Sep-2019	UAE; 19UK003008; Warwickshire; United Kingdom	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: X Sex qualifier: Neutered Age: 4.00 Year(s) Weight: Unknown	7	7	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	N/A	2019*	N/A	D-D	As reported by the animal owner, Merlin a 6 year old male, Ragnar a 5 year old male, Luna a 5 year old female, Vincent a 5 year old male, Morgane a 4 year old female, Abigail a 4 year old female and Rollo a 7 year old male, all neutered Domestic Short Hair felines in good condition and of unknown weights, were administered FRONTLINE PLUS SPOT ON CAT (batch S41113AW expiry AUG 2021) topically by the animal owner, at a dose of 1 dose every 30 days for parasite control. The animal owner applies the product every 30 days as per the instructions, but is seeing fleas this year and has never seen them before. The animal owner saw a flea on the bed this morning. The vets have said that FRONTLINE doesn't work and that animals start to become immune to it. There have been no bites in the household.
06-Sep-2019	UAE; 19UK003015; -; United Kingdom	Species: Feline Breed: Feline various breeds Sex: X Sex qualifier: Unknown Age: 12.00 Year(s) Weight: Unknown	2	2	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	2018*	2018*	N/A	D-D	As reported by the animal owner, Russia a male, and Cassie a female, two 12 year old mixed breed felines weighing average ok by the vet (signalment otherwise unknown) were administered FRONTLINE SPOT ON CAT (batch S21509AX and expiry SEP 2021) topically to the back of the neck by the animal owner in JUL 2019 for an unknown indication. The animal owner reports that they tried the product at two month intervals and unfortunately their cats still have fleas. The animal owner used the product last year and it did not work, but felt that it may have been improved but it has not worked again this year. The animal owner is very disappointed with the results, and feels entitled to a refund and an explanation as to why a product is being sold that does not work. The animal owner reports that they use the product when they see fleas only in the summer, and that they started using the product for their current flea issue in JUL 2019. The last four dates that the animal owner applied the product were the first week of SEP 2019, the first week of AUG 2019 and JUL 2019. People in the home are not being bitten, the animals spend time indoors and outdoors and all animals that live in the household and in contact animals have been treated with a flea product. The animal owner is seeing occasional fleas - less than 5 at the same time, the animals never get bathed or go swimming and the animal owner has regularly vacuumed all areas that the pets can access. On 12 SEP 2019 the animal owner added that they do not have a home infestation. They went to the vets last year as they had fleas and they gave the animals an injection that gets rid of the fleas for 18 months and didn't see any fleas or ticks after that. The animal owner reports that they will not be using FRONTLINE ever again.
08-Sep-2019	UAE; 19UK003016; -; United Kingdom	Species: Feline Breed: Domestic Longhair	1	1	0	Product used: FIPRONIL SPOT ON CAT	N/A	25-Aug-2019	0 Day(s)	D-D	As reported by the animal owner, an approximately 1 year old female neutered Domestic Long Hair feline, was administered FRONTLINE SPOT ON CAT (batch and expiry unknown, details

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 273 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00280

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		(Crossbreed) Sex: F Sex qualifier: Neutered Age: 1.00 Year(s) Weight: Unknown				Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company					unknown) by the animal owner two weeks ago (25 AUG 2019) for an unknown indication. The animal owner reported that the cat became very itchy the same day. The animal owner consistently noted fleas since and has now treated with Comfortis. The animal owner thinks that the animal still has fleas. The house has not been treated and the animal rolls around all day with the neighbour's cat who doesn't look very well looked after. This case is classified as both 'SLEE' and 'Adverse Reaction' but due to a limitation of the database it might be that only the highest hierarchical product problem type, which is 'Adverse Reaction', has been transmitted.
07-Sep-2019	UAE; 19UK003017; -, United Kingdom	Species: Canine Breed: Shih Tzu Sex: M Sex qualifier: Unknown Age: - Weight: 10.4 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: FRONTLINE PETCARE HOME AND ENVIRONMENT FLEA SPRAY; Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a male Shih Tzu canine, weighing 10.4 kg (signalment otherwise unknown) was administered FRONTLINE SPOT ON DOG M (batch and expiry unknown, details unknown) by the animal owner, at a dose of one dose for an unknown indication. The animal owner wants to say how disappointed that they are with the product. Three days after using the product, the animal was full of flea bites. The animal owner used an extra pipette on the animal thinking that it would help, and 4 days later the animal still has fleas. The animal owner reports that it was applied correctly and all the bedding and surrounding areas were also treated with your products (assumed FRONTLINE PETCARE HOMEGARD HOUSEHOLD FLEA SPRAY) and it has done nothing whatsoever. The animal owner has been using the product for some years with success and just finds it strange that since you have brought out a more expensive product called FRONTLINE PLUS, the standard FRONTLINE is no longer working. To that effect the animal owner believes that the MAH have diluted the standard product to get people to pay more for the PLUS product. The animal owner certainly will not be using the product again and will be letting all their family and friends know about it.
07-Sep-2019	UAE; 19UK003018; -, United Kingdom	Species: Canine Breed: Spaniel Sex: M Sex qualifier: Unknown Age: 9.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	N/A	02-Sep-2019	0 Day(s)	D-D	As reported by the animal owner, Alfie, a 9 year old male spaniel (signalment otherwise unknown) was administered FRONTLINE SPOT ON DOG M (batch and expiry unknown) topically to the back of the neck, by the animal owner on 02 SEP 2019 for fleas. The animal owner reports that they were expecting all the fleas to be dead within 24-48 hours but unfortunately he still has fleas. The animal is getting a bit fed up now. The animal owner reported that they treat the pet when they see fleas and when fleas are visible as they have never had a problem with fleas. They first noticed fleas on their pet when the dog returned from the dog sitter after a family holiday. People in the home are not being bitten, the animal spends time indoors and outdoors and all animals in the household and in contact animals have been treated with a flea product. The animal owner is seeing many fleas - more than 5 at the same time, the animal is bathed or goes swimming no more than once a week and the animal owner has treated the home with an environmental flea spray, washed the pet's bedding at over 60 degrees and vacuumed all areas that the pet can access.
08-Sep-2019	UAE; 19UK003019; -, United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: Johnson's 4 Fleas tablets;	N/A	05-Sep-2019	N/A	D-D	As reported by the animal owner, a canine (signalment otherwise unknown) was administered FRONTLINE SPOT ON DOG S (batch, expiry and further details unknown) by the animal owner on 05 SEP 2019 for fleas. The animal owner reports that they recently spotted a couple of fleas on their dog as of Sunday last week (01 SEP 2019). They went to their local pet shop and bought some flea

N/A signifies the information for this field is either not available or not applicable

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Report printed on 25-Oct-2019 at 8:39:59PM

Page 274 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00281

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: - Weight: Unknown				Flea Shampoo; Route: unknown Was the product used ok?: Unknown to Company					shampoo and some Johnson's 4 Fleas tablets on Monday (02 SEP 2019) and bathed the animal in this. The animal owner then went to buy FRONTLINE SPOT ON treatment on Thursday (05 SEP 2019) and applied this. The animal owner stopped the tablets on Wednesday (04 SEP 2019) as they were advised by the company that these tablets only last in the system for 24 hours and so it would be safe to use the spot on. The animal owner has since treated the house (product unknown) and they rebathed the dog last night (07 SEP 2019). However, it is now Sunday (08 SEP 2019) and the dog still seems to be itching. As the animal owner is combing and parting the fur of their dog, there doesn't look to be anything though, although they know that fleas are difficult to see, and their dog does have some more coarse hair areas that are difficult to part and look at. The animal owner wonders how long after using the spot on treatment that they can try another one.
08-Sep-2019	UAE; 19UK003020; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: F Sex qualifier: Neutered Age: 1.00 Year(s) Weight: Unknown	4	4	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	Jul-2019*	Jul-2019*	N/A	D-D	As reported by the animal owner, four neutered female felines, Matilda and Bronte, both aged 17 years, Maggie aged 3 years and Phoebe aged 1 years (signalment otherwise unknown) were administered FRONTLINE PLUS SPOT ON CAT (batch and expiry unknown) from the end of JUL 2019 topically to an unknown site by the animal owner monthly for parasite control. The animal owner reports that they purchased two packets in AUG 2019 and they may as well have put water on their cats. Phoebe was dosed yesterday for the second time in 4 weeks and 24 hours later the animal owner has just combed 10 fleas from her fur. The animal owner asks if there is a problem with the product because it doesn't work and the animal has not been free of fleas. The animal owner states that this is an expensive item and they are not happy that it hasn't worked on any of their four cats. Normally FRONTLINE works fine. On 10 SEP 2019, the animal owner reported that they have used FRONTLINE SPOT ON CAT (batch and expiry unknown) for years and have never had a problem but have moved to FRONTLINE PLUS at the end of JUL as they saw it in a retailer. The animal owner believes it isn't working as well as previously and is not making a blind bit of difference. The animal owner has seen 8 fleas on one cat today (10 SEP 2019) and keeps having to comb them daily. Two people in the house are being bitten. The cats do have access to the outdoors and the animal owner is hoovering every day at the moment. Start date added for submission purposes only. UPDATE 24 OCT 2019: QA results received. Investigation completed for FIPRONIL 10%/S METHOPRENE 12% SPOT ON Lot Unknown, expiry. Final complaint evaluation An adverse event for FRONTLINE PLUS SPOT ON CATS, batch unknown, was received by BIAH QA on the 19th of September 2019. This is the 33rd complaint received for this LOE, in the past 12 months, all batches of Frontline Cat. This defect is rare, it represents 0.2 ppm of every batch produced in 2017 (17 complaints for
08-Sep-2019	UAE; 19UK003021; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: -	2	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other	N/A	08-Sep-2019	N/A	D-D	As reported by the animal owner, approximately 2 cats (signalment otherwise unknown) were administered FRONTLINE PLUS SPOT ON CAT (batch and expiry unknown, details unknown) by the animal owner 7 days ago (01 SEP 2019) for an unknown indication. The animal owner reports that they used FRONTLINE PLUS on their dog and cats 7 days ago and have just seen at least 5 fleas on their cat in one area. The animal owner would like to know why the treatment hasn't worked. They have sprayed the

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 275 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00282

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: Unknown				products Route: unknown Was the product used ok?: Unknown to Company					house and they don't go out.
08-Sep-2019	UAE; 19UK003022; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: F Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	08-Sep-2019	3 Day(s)	D-D	As reported by the animal owner, a female cat (signalment otherwise unknown), was treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), route and frequency unknown, administered by the cat's owner on 05 SEP 2019 and the owner reported on 08 SEP 2019 that the fleas did not seem to be dying. No further information was supplied.
08-Sep-2019	UAE; 19UK003023; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	08-Sep-2019*	23 Day(s)	D-D	As reported by the animal owner, their dogs estimated as 2 dogs (signalment otherwise unknown), were treated with FRONTLINE PLUS SPOT ON DOG (estimated as FRONTLINE PLUS SPOT ON DOG M) batch number and expiry date unknown, route and frequency unknown, administered by the dog's owner on 16 AUG 2019. On 08 SEP 2019 the owner reported that the product did not work. The fleas did not die, the owner presumed that any eggs had hatched and were doubling in number to bother the dogs. The owner had not had any problems in the past and had kept dogs for 40 plus years. No further information was supplied.
09-Sep-2019	UAE; 19UK003035; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a feline (signalment otherwise unknown) was administered FRONTLINE PLUS SPOT ON CAT (batch and expiry unknown, details unknown) by the animal owner, for fleas. The animal owner reports that they used the product on them for 3 months and it hasn't done a thing. They have treated their home numerous times also and every fabric in the house has been washed and sprayed. The animal owner also has a dog which also has fleas (linked case 19UK003036). The animal owner was led to believe FRONTLINE was the best on the market and are very disappointed. Start date added for submission purposes only.
09-Sep-2019	UAE; 19UK003036; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the	N/A	2019*	N/A	D-D	As reported by the animal owner, a canine (signalment otherwise unknown) was administered FRONTLINE PLUS SPOT ON (assumed FRONTLINE PLUS SPOT ON DOG M, batch and expiry unknown, details unknown) by the animal owner, for fleas. The animal owner reports that they used the product for 3 months and it hasn't done a thing. They have treated their home numerous times also and every fabric in the house has been washed and sprayed. The animal owner was led to believe FRONTLINE was the best on the market and are very disappointed. The animal owner also has a cat that has fleas - see linked case 19UK003035. Start date

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 276 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00283

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						product used ok?: Unknown to Company					added for submission purposes only.
09-Sep-2019	UAE; 19UK003038; -; United Kingdom	Species: Feline Breed: Domestic Longhair (Crossbreed) Sex: M Sex qualifier: Neutered Age: 7.00 Year(s) Weight: Unknown	2	2	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	N/A	05-Sep-2019	0 Day(s)	D-D	As reported by the animal owner, Rocky and Tuxi, two 7 year old male neutered Domestic Long Hair felines, of unknown weight and in good condition, were administered FRONTLINE SPOT ON CAT (batch 821509BX expiry SEP 2021) topically to the back of the neck, by the animal owner, at a dose of 1 pipette, on 05 SEP 2019 for an unknown indication. The animal owner reports that they used a different spot on once (nothing prior to this) which did not work and so purchased FRONTLINE and applied it last Thursday (05 SEP 2019). The animal owner was seeing fleas before with the other product that was not working, but is still seeing fleas with FRONTLINE - it is not working. The animal owner asks if the fleas are immune to the product and they have heard that it doesn't work anymore. The animal owner has sprayed the house and used flea powder. The animal owner is not seeing a huge amount of fleas and they are not being bitten, but they have sprayed the bed as one of the animals sleeps on the bed. The animal owner reports that they purchased the product online but that they do not remember where from.
09-Sep-2019	UAE; 19UK003040; -; United Kingdom	Species: Canine Breed: Pomeranian Sex: F Sex qualifier: Unknown Age: - Weight: 8.000 kg*	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	09-Sep-2019*	1 Week(s)	D-D	As reported by the animal owner, a female Pomeranian canine weighing approximately 8 kg (signalment unknown) was given FRONTLINE (assumed FRONTLINE SPOT ON DOG S, batch and expiry unknown) about a week ago (estimated 02 SEP 2019) by the animal owner as a parasiticide (no further information available). The animal owner reports that the dog still keeps scratching and the animal owner can still see live fleas and they are still in the house.
09-Sep-2019	UAE; 19UK003041; -; United Kingdom	Species: Canine Breed: Retriever Labrador Sex: F Sex qualifier: Unknown Age: 2.00 Year(s) Weight: 32 kg	2	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	N/A	09-Sep-2019*	3 Week(s)	D-D	As reported by the animal owner, Mabel a female Labrador canine aged 2 years and weighing 32 kg and in good condition, and another Labrador canine, were given FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG M, batch number S63406AX expiry date NOV 2021) topically to an unknown site by the animal owner 3 weeks ago (estimated as 19 AUG 2019) for an unknown reason. The animal owner reports that they have not seen any fleas on Mabel, she's been scratching a bit but not excessively. The other Labrador definitely doesn't have any fleas. However, Mabel has a few ticks on her face just above her eye. The animal owner thinks they are ticks but they do not look like normal ticks. The animal owner and the dogs live in a very rural area and have lots of land, the dogs are always going down rabbit holes etc. The animal owner does not use the product regularly.
09-Sep-2019	UAE; 19UK003049; -; United Kingdom	Species: Feline Breed: Feline Other Sex: X Sex qualifier: Unknown Age: 4.00 Year(s) Weight: 3 - 5 kg	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical /	13-Jun-2019	05-Aug-2019*	N/A	D-D	As reported by the animal owner, 2 felines, Eli a male moggy aged 4 years and weighing 3 kg, and Stevie a female moggy aged 7 years and weighing 5 kg, both in unknown condition, were given FRONTLINE PLUS SPOT ON CAT (batch number S41113 expiry date SEP 2021) as per their ages every 4 weeks, given topically to the back of the neck by the animal owner for parasite control. The last four dates the cats received the product were 13 JUN 2019, 11 JUL 2019, 05 AUG 2019 and 05 SEP 2019. The animal owner first noticed a problem with fleas in their house 5 weeks ago (estimated

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 277 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

v1.2

ED_005739D_00014390-00284

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Cutaneous Was the product used ok?: Unknown to Company					05 AUG 2019) and the product isn't working. The animal owner has not had a problem with the product until then, when the cats were running with fleas which they brought in the house and infested the house. The animal owner is still finding them and has treated the house with fleas bombs, RIP fleas and has purchased Stronghold from their vet. People in the home are being bitten by fleas, the cats spend time indoors and outdoors, all animals in the house have been treated, the animal owner is seeing occasional fleas (less than 5 fleas) at one time, the home has been treated with 6 flea bombs, the pet's bedding has been washed at over 60 degrees and all areas the pets can access are regularly vacuumed. Stevie is bathed every few days as she has skin allergies, but this does not occur within 2 days of product application. Eli is never bathed. The animals have been banished outside for 2 weeks while they wait to be able to apply Stronghold on them and they are still finding live fleas upstairs. The animal owner states that the issue has been caused categorically, by the failure of the product.
09-Sep-2019	UAE; 19UK003050; Cheshire; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the retail outlet staff member, two canines (signalment otherwise unknown) were administered FRONTLINE PLUS SPOT ON DOG L (batch S63231b and expiry OCT 2021) (details unknown) for an unknown indication. The retail outlet staff member reported that the very upset customer called up as they feel that the product is to blame for the loss of their dog (linked case 19UK003155), their husband potentially losing his job and her near death. The animal owners signed up two of their dogs for FRONTLINE PLUS with a store and have received 3 months of treatment in this time. The animal owner's husband is currently suspended from his job due to having flea bites on his arms as he has to wear short sleeved shirts and his company is not happy with his appearance. The animal owner has nearly passed away from the bites, she has claimed that the bites are septic and that their doctor is visiting her at home due to this. They have had to buy new furniture for the home due to the extent of the fleas. The animal owner has also contracted Lyme Disease from a tick whilst using the product. When asked about the fleas the animal owner claimed that their pets did not have fleas when signing up to the service and this happened suddenly. The animal owner had used numerous sprays and treatments on the home. The reporter states that they haven't managed to get too much information from the animal owner as when questions began they did start to become upset and aggressive. The batch details for the pack provided in store are batch S63231b expiry OCT 2021, and the reporter has requested batch details for the other treatments from their warehouse. Start date added for submission purposes only.
10-Sep-2019	UAE; 19UK003051; -; United Kingdom	Species: Canine Breed: Canine various breeds Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	4	4	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: Fipronil product; Route: unknown Was the product used	N/A	10-Sep-2019	6 Day(s)	D-D	As reported by the animal owner, two Cocker Spaniels and two Pomeranian canines (signalment otherwise unknown), were given FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG M, batch and expiry unknown) on 04 SEP 2019 by the animal owner for parasite control (no further information available). The animal owner reports that they have used fipronil based products (exact products unknown), but not FRONTLINE products, on two dogs and three cats (see linked case 19UK003051) throughout the year, however the pets were all still scratching, so they switched to FRONTLINE PLUS. The animal owner applied the product to the two Cocker Spaniels, three cats and a relation's two Pomeranians on 04 SEP 2019. The animal owner purchased the correct products for each animal's size and weight. The animal owner

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 278 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00285

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						ok?: Unknown to Company					reports that on 10 SEP 2019, 6 days after product application, all the pets are still heavily infested with fleas. The animal owner has been able to pick quite a considerable number of fleas off them and thy can be seen running across the lighter coloured animals.
10-Sep-2019	UAE; 19UK003052; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	3	3	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: Fipronil product; Route: unknown Was the product used ok?: Unknown to Company	N/A	10-Sep-2019	6 Day(s)	D-D	As reported by the animal owner, three felines (signalment otherwise unknown), were given FRONTLINE PLUS SPOT ON CAT (batch and expiry unknown) on 04 SEP 2019 by the animal owner for parasite control (no further information available). The animal owner reports that they have used fipronil based products (exact products unknown), but not FRONTLINE products, on two dogs (see linked case 19UK003051) and the three cats throughout the year, however the pets were all still scratching, so they switched to FRONTLINE PLUS. The animal owner applied the product to the three cats, their two dogs and a relation's two Pomeranians (see linked case 19UK003051) on 04 SEP 2019. The animal owner purchased the correct products for each animal's size and weight. The animal owner reports that on 10 SEP 2019, 6 days after product application, all the pets are still heavily infested with fleas. The animal owner has been able to pick quite a considerable number of fleas off them and thy can be seen running across the lighter coloured animals.
10-Sep-2019	UAE; 19UK003053; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	Sep-2019*	0 Day(s)	D-D	As reported by the animal owner, a approximately one cat (signalment otherwise unknown) was given FRONTLINE PLUS SPOT ON CAT (batch and expiry unknown) for the last two months by the animal owner (no further information available). The animal owner reports that the product has not been effective at all , they have had to get their sofa and pouffe professionally cleaned but they are still riddled in fleas.
10-Sep-2019	UAE; 19UK003056; -; United Kingdom	Species: Canine Breed: Chihuahua Sex: X Sex qualifier: Neutered Age: 6.00 Year(s) Weight: Unknown	3	3	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, Bonnie and Clyde, both aged 7 years and Flocki aged 6 years, all three neutered Chihuahua canines (signalment otherwise unknown) were given FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG S, batch number S62713AW expiry date SEP 2021) topically at an unknown dose every 30 days, by the animal owner for parasite control. The animal owner reports that they apply the product all year round and are now seeing fleas. The product has always worked before. The animal owner does not know how much the dogs weigh, but they are all in good health and are not on any other medications. The animal owner is using a comb to take out all the eggs and is disposing them outside in the garden. The house has been sprayed (product unknown). Start date for submission purposes only.
10-Sep-2019	UAE; 19UK003058; -; United Kingdom	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: U Sex qualifier: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other	N/A	2019*	N/A	D-D	As reported by the animal owner, Jinx (a neutered, 7 year old Domestic Short Hair feline) and Miskha (a neutered, 7 year old Domestic Short Hair feline) (signalment otherwise unknown) were administered FRONTLINE PLUS SPOT ON CAT (batch and expiry unknown) (details unknown) by the animal owner for an unknown indication. The animal owner reports that they have never had fleas and use the product all year round. All in the household are

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 279 of 867

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00286

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: 7.00 Year(s) Weight: Unknown				products Route: unknown Was the product used ok?: Yes					being bitten and the council have been in and sprayed the whole house with pesticide. Start date added for submission purposes only.
07-Sep-2019	UAE; 19UK003062; -; United Kingdom	Species: Canine Breed: Pug Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: Flea shampoo (unspecified); Route: unknown Was the product used ok?: Unknown to Company	N/A	05-Sep-2019*	0 Day(s)	D-D	As reported by the animal owner via social media, Loki, a male Pug canine (signalment otherwise unknown) was administered FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG M, batch and expiry unknown, details unknown) by the animal owner 4 days ago (05 SEP 2019) for an unknown indication. The animal owner reports that they wash their Pug in a flea shampoo and then normally 24 to 48 hours later they use FRONTLINE PLUS on him, but he seems to still itch himself. The animal owner has not seen any fleas on him and asks if this could just be that he is generally itchy, or could the flea treatment not be working for him. The animal owner added that they flead him 4 days ago and he is still itching his side.
10-Sep-2019	UAE; 19UK003063; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-C	As reported by the animal owner via social media, a male canine (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON DOG M, batch and expiry unknown, details unknown) by the animal owner roughly six weeks ago (30 JUL 2019) for an unknown indication. The animal owner reports that the animal had a reaction which resulted in hair loss and hives. The animal was given a course of steroids by the vet which helped. However once the course ended they came back, and so he was given antibiotics and a further course of steroids, which saw a dramatic improvement within days. Now that the medication has come to an end, they are seeing signs of the reaction creeping back.
10-Sep-2019	UAE; 19UK003064; -; United Kingdom	Species: Canine Breed: Terrier (Jack Russell) Sex: M Sex qualifier: Unknown Age: 9.00 Year(s) Weight: 5 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: FRONTLINE PETCARE HOME AND ENVIRONMENT FLEA SPRAY; Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	N/A	25-Aug-2019*	0 Day(s)	D-D	As reported by the animal owner, Barney a 9 year old a male Jack Russell Terrier dog weighing 5 kg, was treated with FRONTLINE PLUS SPOT ON DOGS S (batch number S62709AW and expiry date SEP 2021) topically to the back of the neck, by the animal owner at a dose of 1 dose monthly, last applied on 22 AUG 2019 and again on 25 AUG 2019 for fleas. The owner reported that they had used two lots within one week, the owner had also sprayed the house with FRONTLINE HOMEGARD SPRAY (batch 9254500A expiry SEP 2021) (date used unknown). The owner reported that 2 weeks later on 10 SEP 2019 the dog was still getting fleas, the owner was not happy at all and neither was the dog. The animal owner added that they use the product all year round and that they do not know when they first noticed fleas. People in the home are being bitten, the animal spends time indoors and outdoors and all animals in the household and in contact animals have been treated with a flea product. The animal owner is seeing occasional fleas - less than 5 at the same time - the animal is bathed or goes swimming no more than once a week and the animal owner has treated the home with an environmental flea treatment, washed the pet's bedding at over 60 degrees and regularly vacuumed all areas that the pet can access.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 280 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00287

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
10-Sep-2019	UAE; 19UK003069; -; United Kingdom	Species: Feline Breed: Norwegian Forest Cat Sex: M Sex qualifier: Unknown Age: 16.50 Year(s) Weight: 5.25 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: FRONTLINE PETCARE HOME AND ENVIRONMENT FLEA SPRAY; FIPRONIL SPOT ON CAT; Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	15-Aug-2019	10-Sep-2019	1 Day(s)	D-D	As reported by the animal owner, Theo a male Norwegian cat aged 16 years and 6 months, weighing 5.25 kg was administered FRONTLINE PLUS SPOT ON CAT (batch number: S21204AW and expiry date: AUG 2021) by the animal owner twice over two months due to him having fleas. The owner administered the product by squeezing the pipette until empty in one spot, at the base of the cat's neck, behind the head. The first administration was 15 AUG 2019 after the owner had brushed some flea dirt out of his coat and observed him scratching and meowing. The animal owner reports that the second administration happened yesterday (09 SEP 2019) and yet today (10 SEP 2019) they have brushed out 2 live ones (which they have then killed) and seen another still crawling through the animal's fur, which the animal owner doubts is a lone survivor. The animal owner expected this to kill the fleas on the cat and protect against re-infestation for up to 4 weeks, but in retrospect it hasn't seemed to have done anything for their animal in terms of ridding him of irritation or providing him relief/ normalcy. The animal owner reports that they thought they would bring this to light as it hasn't done what it says on the tin but also because it appears fleas are becoming resistant to the product and thus the MAH should be informed. The owner had also used FRONTLINE PETCARE HOMEGARD HOUSEHOLD FLEA SPRAY for the house and regularly vacuumed all areas the pets can access. The owner had not been bitten by the fleas, the cat is an indoor and outdoor cat, the cat is not bathed and never goes swimming and the owner has lived in their house for more than 1 year. The owner reported that they normally used regular FRONTLINE SPOT ON CAT (last date of application estimated as JUL 2019), but they thought they would try FRONTLINE PLUS to cut the cycle.
10-Sep-2019	UAE; 19UK003071; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	27-Aug-2019	0 Day(s)	D-D	As reported by the animal owner, a canine (signalment otherwise unknown) was administered FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG M, batch and expiry unknown, details unknown) two weeks ago (27 AUG 2019) by the animal owner for an unknown indication. The animal owner reports that they feel that it hasn't worked. They have got a flea collar (dimpylate 15 percent).
11-Sep-2019	UAE; 19UK003074; -; United Kingdom	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: F Sex qualifier: Neutered Age: 11.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: FIPRONIL SPOT ON CAT; Route: Topical / Cutaneous Was the product used ok?: Unknown	10-Aug-2019	27-Jul-2019	N/A	D-D	As reported by the animal owner, an 11 year old female neutered Domestic Short Hair feline, was administered FRONTLINE SPOT ON CAT (batch and expiry unknown, details unknown) by the animal owner for fleas. They started treating the animal in JUL 2019 as their son saw fleas. The animal owner claims that the animal does not go out at all and people in the house are not being bitten. The animal owner gave FRONTLINE SPOT ON on 27 JUL 2019 which was out of date. The animal owner was still seeing one or two fleas and so treated the animal with FRONTLINE SPOT ON CAT (batch S41303AW expiry OCT 2021) topically to an unknown site, by the animal owner twice, 10 AUG 2019 and 09 SEP 2019. The animal owner reports that they are still seeing one or two fleas and is adamant that the animal does not go out. The animal owner has treated the house with a spray three times and added that they

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 281 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00288

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						to Company					live in a semi-rural area and there is lots of wildlife in the area. The animal owner has been putting the fleas in hot water to kill them and stated that the animal had been confined to one room for a while.
11-Sep-2019	UAE; 19UK003081; Nottinghamshire; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: F Sex qualifier: Unknown Age: 15.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: No (Treatment / vaccination program not respected)	N/A	2019*	N/A	D-D	As reported by the animal owner, a 15 year old female feline (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON CAT, batch R40804AW, expiry JUL 2020, further details unknown) by the animal owner for an unknown indication. The animal owner reports that they have always used FRONTLINE on their cat and she has never had fleas. The animal owner thought it was because they were using the product, but this year she got them and they don't know if they got a bad batch but they have not worked. The animal owner has given her all three pipettes over 6 weeks as they didn't work. The animal owner went back to the chemist where they bought them and they said that they had had a few complaints and that a lot of cats had become immune to them. The animal owner adds that if that is right then why isn't it on the packaging, they cannot afford to lose money on something that doesn't work. UPDATE 24 OCT 2019: QA results received. Investigation completed for FIPRONIL SPOT ON CAT Lot R40804AW, expiry 2020-07-31. Final complaint evaluation BIAH QA received a product quality complaint for FRONTLINE Spot on Cat, batch R40804AW, on the 19th September 2019. The complaint description is lack of efficacy. This is the second complaint for this batch. The retention sample is conform (aspect). The sample complaint is not received. No pictures are attached for this case. Batch record investigation: Bulk batch R408 : Manufacturing date: 20/08/17. Expiry date: 07/2020 - Manufacturing quantity: 999 liters No deviation and observation are associated to this batch. This batch was not concerned by any change control. The results of QC testing are conform at specifications. All parameters verified during manufacturing of this batch of bulk are conform. Filling batch R40804 : Manufacturing date: 04/09/2017 Expiry date: 07/2020 - Manufacturing quantity: 50180 blisters of 3 pipettes. No deviation and observation are associated to this batch. This batch was not
11-Sep-2019	UAE; 19UK003082; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: F Sex qualifier: - Age: 7.00 Week(s) Weight: Unknown	2	2	0	Product used: FIPRONIL SPRAY Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	N/A	09-Sep-2019	N/A	D-D	As reported by the animal owner, Sage and Susy, two 7 week old female intact felines in good condition (signalment otherwise unknown), were administered FRONTLINE SPRAY (batch S01906A expiry JUL 2021) topically to an unknown site, at an unknown dose by the animal owner as the animals were covered in fleas. The animal owner recently rehomed the two kittens and they were not previously treated for fleas. The animal owner took them to the vets as they were covered in fleas and purchased FRONTLINE SPRAY which was used two days ago. The vet advised that the fleas would die within 24 hours but they are still covered 2 days later. The animal owner asked if they should spray them again. The animal owner can see dead fleas but also lots of live ones still. There are two older cats that also live in the home and these are treated monthly throughout the year (product unknown). The animal owner is hoovering and washing bedding, and was keeping the kittens in the kitchen.
11-Sep-2019	UAE; 19UK003085; -; United Kingdom	Species: Canine Breed: Terrier (Jack Russell)	1	1	0	Product used: FIPRONIL 10%/S	30-Aug-2019	30-Aug-2019*	N/A	D-D	As reported by the animal owner, Wilfred, a 20 year old male neutered Jack Russell Terrier canine, weighing approximately 7.6 kg, was administered FRONTLINE PLUS SPOT ON DOG S (batch

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 282 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00289

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex: M Sex qualifier: Unknown Age: 20.00 Year(s) Weight: 7.6 kg*				METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company					and expiry unknown, details unknown) topically to the back of the neck, by the animal owner, at a dose of two doses, as they saw a flea in the animal's coat. The animal owner reports that they have followed the instructions and unfortunately the FRONTLINE PLUS for small dogs isn't working. They have done a second application but the animal is still troubled with fleas. The animal was bathed 48 hours after the first application and flea combed. The animal owner adds that they treat the animal around every 3 to 6 months or when they see fleas. They first started treating the animal for the current flea issue around 2 to 3 weeks ago. The last dates that the animal owner applied the product to the animal were 08 SEP 2019 and 30 AUG 2019. The animal spends time indoors and outdoors, all animals in the household and in contact animals have been treated with a flea product and the animal owner is seeing occasional fleas - less than 5 at the same time. No one in the home is being bitten. The animal does not get bathed or swim within 2 days of product administration and the animal owner has treated the home with an environmental flea treatment, washed the pet's bedding at over 60 degrees and regularly vacuumed all areas that the pet can access. Start date added for submission purposes only.
11-Sep-2019	UAE; 19UK003086; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a canine (signalment otherwise unknown) was administered FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG M, batch and expiry unknown, details unknown) by the animal owner at a dose of 2 doses, for an unknown indication. The animal owner reports that they have still got problems with fleas on their dog. They have used two FRONTLINE PLUS treatments and it is not making any difference. Start date added for submission purposes only.
11-Sep-2019	UAE; 19UK003087; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	3	3	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: No (Treatment / vaccination program not respected)	N/A	2019*	N/A	D-D	As reported by the animal owner, three felines (signalment otherwise unknown) were administered FRONTLINE (assumed FRONTLINE SPOT ON CAT, batch and expiry unknown, details unknown) by the animal owner as they had contracted fleas. The animal owner followed the instructions and treated all three cats. That evening they seemed extra itchy and so the animal owner was hoping that the treatment had worked. Over the next few days the animals were still showing signs of still having fleas. The animal owner checked online to see how long the product should take to eradicate the fleas and realised that it hadn't worked. A week later again the animal owner bought a pack of three pipettes from their local pet shop and again treated all three cats. Yet again they still have fleas. The animal owner asks if the product has stopped working as it definitely hasn't worked in their case. The animal owner also treated the home and vacuumed every day. the animal owner asks how the MAH is still selling a product that purports to kill fleas etc when it obviously doesn't. Having read up on the product the animal owner has seen a few other cat owners complaining of the same issue. The animal owner has wasted money and still has uncomfortable itchy cats. Start date added for submission purposes only.
12-Sep-2019	UAE; 19UK003097;	Species: Feline Breed: Domestic	4	4	0	Product used: FIPRONIL	N/A	Apr-2019*	N/A	D-D	As reported by the animal owner, Tony a male, and Jessy, Mittens and Cora, four Short Hair felines weighing approximately 4 kg,

N/A signifies the information for this field is either not available or not applicable

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Report printed on 25-Oct-2019 at 8:39:59PM

Page 283 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00290

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	-; United Kingdom	Shorthair (Crossbreed) Sex: X Sex qualifier: Unknown Age: - Weight: 4 kg*				10%/S METHOPRENE 12% SPOT ON Other products used: Advantage; Route: Topical / Cutaneous Was the product used ok?: Unknown to Company					were administered FRONTLINE PLUS SPOT ON CAT (batch and expiry unknown) topically to the nape of the neck, by the animal owner for parasite control. The animal owner reported that they bought Advantage 4 times and then FRONTLINE PLUS twice. They used the FRONTLINE PLUS approximately 2 weeks ago and it has done nothing, nor did the Advantage. The animal owner has 4 cats and they are buying four pipettes each time, if anything it has made it worse. The animal owner really doesn't think that the product is working and either the fleas have become immune to the ingredients or there is a problem with the ratio. The animal owner does not think that they will be attempting to use a FRONTLINE product again as over the last 5 months they have spend a lot of money and not once eliminated any fleas. The animal owner added that they apply the product monthly but not during winter and that they started using the product for the current flea issue in APR 2019, as well as first noticing fleas in APR 2019. The animal owner states that they will flea bomb the house at the end of the summer and use a spray as well. The last four dates that the animal owner applied the product were AUG 2019, JUL 2019, JUN 2019 and APR 2019, people are not being bitten in the home, the animals spend time indoors only and they have seen many fleas – 5 or more at the same time. The animals are never bathed nor go swimming and the animal owner has treated the home with an environmental flea treatment, washed their bedding at over 60 degrees and regularly vacuumed and notes that downstairs has no carpets it is wood laminate. Start date added for submission purposes.
12-Sep-2019	UAE; 19UK003098; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a male canine (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON DOG M), batch and expiry unknown, details unknown) by the animal owner for an unknown indication. The animal owner reports that they have just visited the vet as their dog has itchy skin. He has no fleas as they use FRONTLINE regularly but the vet said that it is the worst flea treatment on the market and charged the animal owner for a flea tablet. Start date added for submission purposes only.
12-Sep-2019	UAE; 19UK003105; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	12-Sep-2019*	4 Week(s)	D-D	As reported by the animal owner, a feline (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON CAT, batch and expiry unknown, details unknown) by the animal owner as a flea and tick treatment. The animal owner asked how often you can use FRONTLINE flea and tick treatment on cats as they used the treatment 4 weeks ago and their cat has fleas again.
12-Sep-2019	UAE; 19UK003106; -; United Kingdom	Species: Canine Breed: Cavalier King Charles Sex: M Sex qualifier: Neutered	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products	N/A	2019*	N/A	D-D	As reported by the animal owner, Benji a 2 year old male neutered Cavalier King Charles Spaniel canine, weighing 10 kg and in good condition, was administered FRONTLINE PLUS SPOT ON DOG S (batch VM08327 expiry SEP 2021) topically to an unknown site, by the animal owner, at a dose of 1 dose every 30 days, for an unknown indication. The animal owner reports that on 06 SEP 2019 they went to their local vet who gave them Advocate. The

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 284 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

v1.2

ED_005739D_00014390-00291

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: 2.00 Year(s) Weight: 10 kg				used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes					animal owner is being bitten at home and wants a refund for the FRONTLINE PLUS. Start date added for submission purposes only.
13-Sep-2019	UAE; 19UK0031110; Pembrokeshire; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: F Sex qualifier: Neutered Age: 2.00 Year(s) Weight: Unknown	4	4	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	N/A	06-Sep-2019*	0 Day(s)	D-D	As reported by the animal owner, four neutered female felines, Suki aged 4 years, Marley aged 5 years, Ziggy aged 3 years and Cookie aged 2 years (signalments otherwise unknown) were given FRONTLINE SPOT ON CAT (batch number S21509BX expiry date SEP 2021) on 06 SEP 2019 topically to an unknown site by the animal owner as a parasiticide. The animal owner reports that they usually purchase the product from their vet but saw an offer from a retailer so purchased them from there. Since using the product, the animal owner is now seeing fleas and believes the product isn't doing anything. The animal owner is seeing 2 or 3 fleas and the cats are itching. The animal owner has been using FRONTLINE in the warmer months. The animal owner is not being bitten and they are treating the home to be safe. Their vet has advised that they may have used a fake product. The animal owner says that the product doesn't have the usual smell and seems to be a different consistency, and the pipettes look different too. UPDATE 23 OCT 2019: QA results received. Investigation completed for FIPRONIL SPOT ON CAT Lot S21509BX, expiry 2021-09-30. Final complaint evaluation BIAH QA received a product quality complaint for FRONTLINE spot on cat, batch S21509BX, on the 24th of September 2019. The complaint description is unusual smell and consistency, lack of efficacy. This is the second complaint regarding these defects for this batch. The retention sample is conform (aspect) but it is only possible to open the blister package in the case of a critical defect. The complaint sample had been received. The consistency and odor of complaint sample are conform. The product is genuine. Batch record investigation: bulk batch S215 Manufacturing date: 17/10/2018 - Expiry date: 09/2021 - Manufacturing quantity: 1199.4 liters. No deviation associated to this batch and one observation is associated to this batch and not related to this defect. This batch was not concerned by any change control. The results
13-Sep-2019	UAE; 19UK0031117; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: Household flea treatment; Route: unknown Was the product used ok?: Yes	N/A	2019*	9 Week(s) 3 Day(s)	D-D	As reported by the animal owner, a dog (signalment otherwise unknown), was treated with FRONTLINE PLUS (estimated as FRONTLINE PLUS SPOT ON DOGS M) batch number and expiry date unknown, route and frequency unknown, administered by the dog's owner 8 weeks previous to the date of the report (date of administration estimated as 19 JUL 2019). On 13 SEP 2019 the owner reported that the fleas were not dying, if anything the situation had worsened, the product was not working. They had followed the instructions and had treated the house as well. The owner reported that to be paying that type of money and for the product not to work at all, seemed a disgrace. They hated to see their animal struggling with fleas, it was torture, but they now could not put anything on them for another eight weeks. No further information was supplied. Case linked to 19UK003118.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 285 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00292

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
13-Sep-2019	UAE; 19UK003118; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: Household flea treatment; Route: unknown Was the product used ok?: Yes	N/A	13-Sep-2019	8 Week(s)	D-D	As reported by the animal owner, their cat's, estimated as 2 cat's (signalment otherwise unknown), were treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), route and frequency unknown, administered by the cat's owner 8 weeks previous to the date of the report (date of administration estimated as 19 JUL 2019). On 13 SEP 2019 the owner reported that the fleas were not dying, if anything the situation had worsened, the product was not working. They had followed the instructions and had treated the house as well. The owner reported that to be paying that type of money and for the product not to work at all, seemed a disgrace. They hated to see their animal's struggling with fleas, it's was torture, but they now could not put anything on them for another eight weeks. No further information was supplied. Case linked to 19UK003117.
15-Sep-2019	UAE; 19UK003121; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner via Social media, a male canine (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON DOG M, batch and expiry unknown, details unknown) topically to an unknown site by the animal owner for an unknown indication. The animal owner reports that they used the product on their dog and it hasn't done anything. They placed the liquid directly onto the dog's skin. They have sprayed the house and the dog has been kept in an area of the house with only hard floors. The animal owner is vacuuming twice a day and washing all his bedding and fabrics every day. There has been no reduction of fleas on the dog at all and they have found no dead fleas. It simply hasn't worked. Start date added for submission purposes only.
15-Sep-2019	UAE; 19UK003122; -; United Kingdom	Species: Canine Breed: Staffordshire Terrier (American) Sex: U Sex qualifier: Unknown Age: 10.00 Year(s) Weight: 18 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	Apr-2019*	05-Sep-2019	0 Day(s)	D-D	As reported by the animal owner via social media, Rocky a Staffordshire Bull Terrier canine aged 10 years and weighing 18 kg (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON DOG M, batch and expiry unknown) topically to the shoulder blades ten days ago (05 SEP 2019) by the animal owner for an unknown indication. The animal owner asks if they should put this on vertically or horizontally on the shoulder blades as the videos show both, and if they can put any near the base of the tail if they are with the dog all day. Their dog is still scratching after ten days and they ask if they should reapply. On 16 SEP 2019 the animal owner reported that they apply a flea product every two months and only treat in the summer. The last dates the product was used were APR 2019, JUN 2019 and SEP 2019. The animal owner started seeing fleas on 05 SEP 2019. People in the house were being bitten but not now. The animal owner has only seen 1 large flea. The product was not applied while the pet were wearing a collar, the dog does not get bathed or go swimming within 2 days of product application, the animal owner has not lived in the home for less than a year. The home has been treated with Indorex spray, the pet's bedding has been washed at over 60 degrees and all areas the pets can access have not been regularly vacuumed. The animal owner added that they have only had fleas now in all the 12 years that they have had dogs.
13-Sep-2019	UAE; 19UK003123; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier:	2	2	0	Product used: FIPRONIL SPOT ON CAT Other products used: Indorex;	Jun-2019*	2019*	0 Day(s)	D-D	As reported by the animal owner, their cats, estimated as 2 cats (signalment otherwise unknown) were treated with FRONTLINE SPOT ON CAT, batch number and expiry date unknown, route unknown, administered by the cat's owner every 3 weeks for the last 3 months (last application date estimated as SEP 2019). The

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 286 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).
Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.
Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00293

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Unknown Age: - Weight: Unknown				Route: unknown Was the product used ok?: Unknown to Company					owner had used 2 whole cans of Indorex in the home, as well as vacuuming and washing the pet and human bedding, but there were still flea eggs dropping off from the cats.
15-Sep-2019	UAE; 19UK003124; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: M Sex qualifier: Unknown Age: - Weight: 58 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a male canine weighing 58 kg (signalment otherwise unknown) was administered FRONTLINE PLUS SPOT ON DOG XL (batch and expiry unknown, details unknown) by the animal owner for biting lice. The animal owner reports that they recently bought the product for their dog as they had noticed him scratching and on examination saw biting lice. They applied the product as directed, however four days since there are still biting lice on the animal. Start date added for submission purposes only.
13-Sep-2019	UAE; 19UK003127; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: F Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	N/A	13-Sep-2019	N/A	D-C	As reported by the animal owner, a female dog (signalment otherwise unknown), was treated with FRONTLINE PLUS (estimated as FRONTLINE PLUS SPOT ON DOGS M) batch number and expiry date unknown, applied topically to the cat by the owner on an unknown date. On 13 SEP 2019 the owner reported that the dog now has sores and burn marks where the product was applied, which resulted in a trip to the vets. The owner was disgusted that they had to put their dog through that. The dog also kept yelping when the owner applied it.
16-Sep-2019	UAE; 19UK003128; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	May-2019*	May-2019*	N/A	D-D	As reported by the animal owner, a feline (signalment otherwise unknown) was administered FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON CAT, batch and expiry unknown, details unknown) by the animal owner for 4 months (start day MAY 2019) for an unknown indication. The animal owner reports that they have an indoor cat and they have been using FRONTLINE PLUS for four months now and if anything the fleas have multiplied. There is no way that they could have a bad infestation as their cat doesn't even go out and it is the first time they have had fleas. The animal owner is extremely angry and upset with this - it is causing their pet and their family a great deal of stress. The animal owner believes that it should have worked by now or at least killed some of them. There is also a dog in the household - see linked case 19UK003129.
16-Sep-2019	UAE; 19UK003129; -; United Kingdom	Species: Canine Breed: West Highland White Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the	May-2019*	May-2019*	N/A	D-D	As reported by the animal owner, a West Highland White canine (signalment otherwise unknown) was administered FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG M, batch and expiry unknown, details unknown) by the animal owner for 4 months (start day MAY 2019) for an unknown indication. The animal owner reports that they have been using FRONTLINE PLUS for four months now and if anything the fleas have multiplied. The animal owner also has a cat (see linked case

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 287 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00294

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						product used ok?: Unknown to Company					19UK003128) and there is no way that they could have a bad infestation as their cat doesn't even go out and it is the first time they have had fleas. The animal owner is extremely angry and upset with this - it is causing their pet and their family a great deal of stress. The animal owner believes that it should have worked by now or at least killed some of them.
13-Sep-2019	UAE; 19UK003130; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	Sep-2019*	N/A	D-D	As reported by the animal owner, their cats (estimated as 2 cats, signalment otherwise unknown) were treated with FRONTLINE SPOT ON CAT (batch number and expiry date unknown), route and frequency unknown, administered by the cat's owner, on an unknown date and the owner still found fleas, so the treatment was repeated again after a 2 week interval only, as the situation had become unbearable. The owner had hot washed all the soft furnishings and had still have found living fleas on the cats. The date of the event was added for submission purposes only.
13-Sep-2019	UAE; 19UK003131; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: M Sex qualifier: Unknown Age: 14.00 Year(s) Weight: 4 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: FRONTLINE PETCARE HOME AND ENVIRONMENT FLEA SPRAY; Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	Mar-2019*	13-Sep-2019*	3 Week(s)	D-D	As reported by the animal owner, Twix, a 14 year old male cat weighing 4 kg (signalment otherwise unknown), was treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), topically to the back of the neck, administered by the cat's owner every month since MAR 2019 to control the fleas on the cat. The owner reported that, unfortunately, the cat had experienced the worst case of fleas that summer, the owner was even finding fleas in their home, which had become so bad that the owner thought they may need to call Rentokil. The owner last treated the cat three weeks ago (date estimated as 23 AUG 2019). The cat was asleep today (13 SEP 2019) so the owner took the opportunity to check the cat for fleas, immediately they came across at least five near the cat's ears. The owner thought that this was probably just the tip of the iceberg. The owner wanted to know why the flea treatment was not working, and felt that they had wasted their money and would now need to pay out for pest control. The animal owner added that they treat the animal monthly all year round and that they noticed fleas on their pet in the summer when they started to get bitten. The last four dates that the product was applied were 02 SEP 2019, 02 AUG 2019, 02 JUL 2019 and 02 JUN 2019 and people in the home are being bitten. The animal spends time indoors and outdoors, all animals in the home and in-contact animals have been treated with a flea product and the animal owner is seeing many fleas - more than 5 at the same time. The animal is never bathed nor goes swimming and the animal owner has treated the home with an environmental flea treatment (FRONTLINE PETCARE HOMEGARD HOUSEHOLD FLEA SPRAY) (batch and expiry unknown), washed the pet's bedding at over 60 degrees and regularly vacuumed all areas that the pet can access.
14-Sep-2019	UAE; 19UK003132; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: M Sex qualifier: Unknown Age: 12.00 Year(s)	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: FIPRONIL	N/A	14-Sep-2019	N/A	D-D	As reported by the animal owner, a male 12 year old, rescue cat weighing 10 lb (4.5 kg), was treated with FRONTLINE PLUS SPOT ON CAT (batch number and expiry date unknown), topically to the top of the neck, administered by the cat's owner on an unknown date and the owner reported on 14 Sep 2019 that the cat still has fleas. The fleas were jumping around the owner's home and the cat was very uncomfortable. The owner had been buying

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 288 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00295

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: 10 lbs				SPOT ON CAT; Route: Topical / Cutaneous Was the product used ok?: Unknown to Company					FRONTLINE for years but the chemist had told the owner that it does not work anymore so the owner had bought FRONTLINE PLUS. The animal owner added that they haven't bathed their cat, that he is an indoor cat and they normally FRONTLINE him every three months on the top of his neck. The animal doesn't see any other animals. The owner reported that they are getting bitten too and is hoovering 4 times a day. The animal owner is devastated as they have always used FRONTLINE and it is not working.
15-Sep-2019	UAE; 19UK003133; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	15-Sep-2019	10 Day(s)	D-D	As reported by the animal owner, their 2 cats (signalment otherwise unknown) were treated with FRONTLINE (assumed to be FRONTLINE SPOT ON CAT) batch number and expiry date unknown, route and frequency unknown, administered by the cat's owner monthly, last administered 10 days ago (date estimated as 05 SEP 2019). On 15 SEP 2019 the owner reported that the product clearly had not worked, one cat was scratching all the time and the owner could see a lot of fleas on them.
15-Sep-2019	UAE; 19UK003138; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	within 2 hours	D-C	As reported by the animal owner, Lola, a feline (signalment otherwise unknown) was administered FRONTLINE SPOT ON CAT (batch and expiry unknown, details unknown) by the animal owner for a unknown indication. The animal owner reports that they use spot on treatments all the time, but this time it has caused severe burns to their cat. The animal is in severe distress after this treatment. The animal owner reports that the adverse reaction started within hours of applying. The veterinary practice reported that they have not seen the animal since 2015. Start date added for submission purposes only.
15-Sep-2019	UAE; 19UK003139; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	4	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-C	As reported by the animal owner, four felines (signalment otherwise unknown) were administered FRONTLINE (assumed FRONTLINE SPOT ON CAT, batch and expiry unknown, details unknown) by the animal owner for an unknown indication. The animal owner reports that they have four cats and they have used FRONTLINE before. The last time, it caused the hair to fall out and burned the skin of one of the cats, Simba. They tried again this time and used a little less, but it had the same result on one of their cats, which was the same one as last time. It was fine on the other three cats. The veterinary practice have not seen the animal for an adverse reaction and have never sold the animal owner FRONTLINE. Start date added for submission purposes only.
16-Sep-2019	UAE; 19UK003145; -; United Kingdom	Species: Canine Breed: Canine (DO NOT USE) Sex: U Sex qualifier: Unknown Age: - Weight: 6 kg	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, two canines weighing 6 kg (signalment otherwise unknown) were administered FRONTLINE PLUS SPOT ON DOG S (batch S60812AL, expiry MAR 2021, details unknown) by the animal owner for fleas. The animal owner reports that they have two dogs and both have recently picked up fleas whilst using the product. Both dogs weigh 6 kg and even after an additional application there has been no effect. The animal owner has used the products regularly and up until this it has always worked. Start date added for submission purposes only.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 289 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00296

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
16-Sep-2019	UAE; 19UK003148; -; United Kingdom	Species: Canine Breed: Greyhound Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: Indorex Defence Spray 500ml; Route: unknown Was the product used ok?: Unknown to Company	Jul-2019	Jul-2019*	N/A	D-D	As reported by the animal owner, their 2 Greyhound dogs, weighing under 40 kg (signalment otherwise unknown) were treated with FRONTLINE PLUS SPOT ON DOGS L (batch number: S61811 and expiry date: JUN 2021), 1 pipette used for each dog, administered by the dog's owner, date of application assumed to be JUL 2019, when the owner first purchased the 3 pipette version. At the same time the owner also purchased a spray can of Virbac Indorex Defence Spray 500ml to treat the house and the dog's bedding etc, under the advice of the store owner in conjunction with the FRONTLINE PLUS. The owner sprayed the whole house, bedding and everything as directed. The owner reported that both the dogs were still riddled with fleas 2 weeks later. The owner sprayed the house a second time, as the owner could not treat the dogs with anything else for another 2 weeks. Still, the dogs had fleas and nothing appeared to have died at all. They could not get rid of the fleas on the dogs at all and at no time did any of the fleas on them die. So, the owner was now going to have to take Veterinary advice as to how to get rid of them. The owner reported that in the past it the product had worked perfectly.
17-Sep-2019	UAE; 19UK003154; -; United Kingdom	Species: Canine Breed: Terrier (Jack Russell) Sex: F Sex qualifier: Neutered Age: 7.00 Year(s) Weight: 9.2 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: FIPRONIL SPOT ON DOG; Route: Topical / Cutaneous Was the product used ok?: Yes	N/A	20-Aug-2019	1 Day(s)	D-B	As reported by the staff member at the retail outlet, a canine (signalment otherwise unknown) was administered FRONTLINE PLUS SPOT ON DOG S) (batch S62713AW expiry SEP 2021) (details unknown) for an unknown indication. The staff member reported that they purchased the product on 19 AUG 2019 and they don't know when the animal owner applied it to the dog. The animal owner came into the shop angry and waving the vet bill. The animal owner wanted compensation for the treatment, and the animal owner just said that the dog reacted to FRONTLINE PLUS. The animal had nearly died and he had had to have a week off work to look after it. The staff member said that they couldn't take details from the animal owner, but that he did remember that the animal owner said that the animal went numb all down one side. The animal owner then reported that the animal is Willow, a 7 year old female neutered Jack Russell Terrier cross canine, weighing 9.7 kg and in good condition, and that they applied the product on 19 AUG 2019 at a dose of 1 pipette, topically to an unknown site for a flea infestation. The animal is allergic to fleas and has generally itchy skin. The animal was fine on the day of application and then the second day (20 AUG 2019) around teatime she became lethargic, wouldn't respond and collapsed. They rushed to the vets and they were closed and so the out of hours vet came to the practice. The animal owner said that the animal was on the verge of dying and that the vet asked if they had thought about euthanasia. The left side wasn't responding very well. However the animal was not hospitalised and the vets said to wash the product off her at home. The animal owner said that the animal could not have licked the product and he has been putting it on for years. The animal owner made an appointment for the next day and the animal was much better, but the left side was still not responding as well as the right. The vet said to monitor and so that meant he had to take the whole
09-Sep-2019	UAE; 19UK003155; Cheshire; United Kingdom	Species: Canine Breed: Terrier Breeds (500 Series)	1	1	1	Product used: FIPRONIL 10%/S METHOPRENE	N/A	2019*	N/A	D-A	As reported by the retail outlet staff member, a small terrier canine (signalment otherwise unknown) was administered one of the products belonging to the MAH (assumed FRONTLINE PLUS SPOT ON DOG S) (details unknown) for an unknown indication.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 290 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00297

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex: U Sex qualifier: Unknown Age: - Weight: Unknown				9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company					The retail outlet staff member reported that the very upset customer called up as they feel that the product is to blame for the loss of their dog, their husband potentially losing his job and her near death. The animal owners signed up two of their other canines (signalment otherwise unknown) for FRONTLINE PLUS SPOT ON DOG L with a store and have received 3 months of treatment in this time. One of their dogs, a small terrier (never on the subscription) has apparently passed away from fleas after using the products. The fleas entered his brain and caused neurological problems. The animal owner's husband is currently suspended from his job due to having flea bites on his arms as he has to wear short sleeved shirts and his company is not happy with his appearance. The animal owner has nearly passed away from the bites, she has claimed that the bites are septic and that their doctor is visiting her at home due to this. They have had to buy new furniture for the home due to the extent of the fleas. The animal owner has also contracted Lyme Disease from a tick whilst using the product. When asked about the fleas the animal owner claimed that their pets did not have fleas when signing up to the service and this happened suddenly. The animal owner had used numerous sprays and treatments on the home. The reporter states that they haven't managed to get too much information from the animal owner as when questions began they did start to become upset and aggressive. Start date added for submission purposes only. This case is linked to 19UK003050. UPDATE from authority 30 SEP 2019: VMD update: this has been reported as a lack of efficacy so it has been changed to LEE . Veddra added for LEE and deleted for neurological signs .
17-Sep-2019	UAE; 19UK003156; -, United Kingdom	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: F Sex qualifier: - Age: 18.00 Week(s) Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	06-Sep-2019	06-Sep-2019	0 Day(s)	D-D	As reported by the animal owner, Smudge an intact female domestic Shorthair feline aged 18 weeks and in good condition (weight unknown) was given FRONTLINE PLUS SPOT ON CAT (batch number S41306AW expiry date OCT 2021) on 06 SEP 2019 topically to the back of the neck by the animal owner as a parasiticide. The animal owner reports that they saw fleas so applied the product. They are still seeing fleas and the product hasn't worked. The animal owner is getting about 9-14 fleas off the cat at a time. The cat does not go outside. The animal owner got the kitten from a friend. No one in the house is being bitten.
17-Sep-2019	UAE; 19UK003159; -, United Kingdom	Species: Feline Breed: Feline (unknown) Sex: F Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: House spray (unspecified); Route: unknown Was the product used ok?: Unknown to Company	N/A	13-Sep-2019	0 Day(s)	D-D	As reported by the animal owner, a female cat (signalment otherwise unknown), was treated with FRONTLINE SPOT ON CAT (batch number and expiry date unknown), route and frequency unknown, administered by the cat's owner on approximately 13 SEP 2019. On 17 SEP 2019 (4 days later) the owner reported that the cat still had fleas. The owner was treating the house pretty much every day with sprays and hoovering, but the cat still had fleas and lots of eggs.
17-Sep-2019	UAE; 19UK003161;	Species: Canine	1	1	0	Product used:	N/A	Sep-2019*	N/A	D-D	As reported by the animal owner, a dog (signalment otherwise unknown), was treated with FRONTLINE SPOT ON DOG S (batch

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 291 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00298

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	-; United Kingdom	Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown				FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company					number and expiry date unknown), route and frequency unknown, administered by the dog's owner on an unknown date and again two weeks later. On 17 Sep 2019 the owner reported that it had absolutely no effect whatsoever, even after the second application, it still did not work. On 20 SEP 2019 the animal owner reported that they have had dogs for a long time and understand about fleas. They know when a spot on is working and when it's not and the fact is that FRONTLINE SPOT ON is no longer effective on their dog for whatever reason. The animal owner has looked around different forums and the number of people that complain about this issue is amazing. The animal owner has used this product in the past with no problems but recently it has been entirely non effective.
18-Sep-2019	UAE; 19UK003168; -; United Kingdom	Species: Canine Breed: Basset Hound Sex: F Sex qualifier: Unknown Age: 7.00 Year(s) Weight: 30 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	15-Jul-2019*	Jul-2019*	N/A	D-D	As reported by the animal owner, Shirley Basset, a 7 year old female Basset Hound canine, weighing 30 kg and in unknown condition, was given FRONTLINE SPOT ON DOG L (batch and expiry unknown) from mid JUL 2019, by the animal owner as a parasiticide. The animal owner reports that they have used the product strictly as per the instructions on the packet and their dog still has fleas. The dog does not come into contact with cats and the house has been treated. The animal owner used a second application which also did not work. The animal owner added that they use the product all year round and that they started using the product for their current flea issue in JUL 2019. They first noticed fleas on their pet in JUL 2019 and they applied the product in the middle of JUL 2019 and the middle of AUG 2019 (after 5 weeks from the first dose). People in the home are being bitten, the animal spends time indoors and outdoors and all animals in the household and in contact animals have been treated with a flea product. The animal owner is seeing many fleas - more than 5 at the same time, the animal is never bathed and the animal owner has treated the home with an environmental flea treatment, washed the pet's bedding at over 60 degrees and regularly vacuumed all areas that the pet can access. The animal owner reports that they researched the flea products on the market prior to purchasing FRONTLINE and chose FRONTLINE as being the most effective. The animal owner adds that they do not have any other pets and once the fleas were noticed and the animal treated, the home was treated also to prevent an infestation. The animal owner did see what appeared to be an increase in fleas after the first treatment, which they expected, but when they applied the second treatment, given the house had been treated, they expected the second treatment to have killed any remaining fleas. The animal owner appears to be the only person in the house whom the fleas are interested in, having been bitten
17-Sep-2019	UAE; 19UK003170; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	3	3	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	10-Sep-2019	N/A	D-D	As reported by the animal owner, three small canines (signalment otherwise unknown) were administered FRONTLINE (assumed FRONTLINE SPOT ON DOG S, batch and expiry unknown, details unknown) by the animal owner on 10 SEP 2019 for an unknown indication. The animal owner reported that they put the FRONTLINE on them all and they still have fleas. They have washed all the bedding, de flead the house over and over and they are combing constantly.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 292 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00299

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
18-Sep-2019	UAE; 19UK003177; Norfolk; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: PO-Oral Was the product used ok?: No (Route not indicated / recommended)	N/A	2019*	1 Day(s)	D-B	As reported by the attending veterinary surgeon, an unknown number of dogs (estimated to be 2, signalment otherwise unknown) were administered FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG M, batch and expiry unknown, details unknown) for an unknown indication. Referring to linked case 19UK003154, the attending vet reported that they have seen this type of reaction before in dogs that have ingested the product - neurological signs, dazed/out of it, with some knuckling. Start date for submission purposes only.
19-Sep-2019	UAE; 19UK003179; -; United Kingdom	Species: Canine Breed: Poodle (Standard) Sex: F Sex qualifier: Neutered Age: 13.00 Year(s) Weight: 20 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	2009*	Sep-2019*	26 Day(s)	D-D	As reported by the animal owner, Prudy, a neutered female Poodle canine aged 13 years and weighing 20 kg, and in good condition, was given FRONTLINE PLUS SPOT ON DOG L (batch number S63506AX expiry date NOV 2021) from 2009 every 30 days, applied topically by the animal owner for parasite control. The animal owner reports that they have used the product for 10 years and have never had a problem. They are not being bitten in the home, they are going to manage the fleas by going to the vets this afternoon (19 SEP 2019), the dog has sore skin at the moment. They also have another dog (see linked case 19UK003180). Start date for submission purposes only.
19-Sep-2019	UAE; 19UK003180; -; United Kingdom	Species: Canine Breed: Poodle (Toy) Sex: F Sex qualifier: Neutered Age: 8.00 Year(s) Weight: 10 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	2011*	Sep-2019*	26 Day(s)	D-D	As reported by the animal owner, Freya, a neutered female Toy Poodle canine aged 8 years and weighing 10 kg, and in unknown condition, was given FRONTLINE PLUS SPOT ON DOG M (batch number S62709AW expiry date SEP 2021) from 2011 every 30 days, applied topically by the animal owner for parasite control. The animal owner reports that they have used the product for 10 years and have never had a problem. They are not being bitten in the home, they are going to manage the fleas by going to the vets this afternoon (19 SEP 2019), the dog has sore skin at the moment. They also have another dog (see linked case 19UK003179). Start date for submission purposes only.
19-Sep-2019	UAE; 19UK003190; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL SPOT ON CAT Other products used: FRONTLINE PETCARE HOME AND ENVIRONMENT FLEA SPRAY; Route: unknown Was the product used ok?: Unknown	N/A	05-Sep-2019	0 Day(s)	D-D	As reported by the animal owner, two felines (signalment otherwise unknown) were administered FRONTLINE SPOT ON CAT (batch and expiry unknown) (details unknown) by the animal owner for an unknown indication. The animal owner reports that they used FRONTLINE SPOT ON on their two cats and FRONTLINE PETCARE HOMEGARD HOUSEHOLD FLEA SPRAY all over the house. Two weeks on and it is as bad as ever.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 293 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00300

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
19-Sep-2019	UAE; 19UK003191; Nottinghamshire; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: M Sex qualifier: Unknown Age: 7.00 Year(s) Weight: 4.5 kg	1	1	0	to Company Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	Aug-2019*	Aug-2019*	N/A	D-D	As reported by the animal owner, Ethel, an approximately 7 year old male feline weighing 4.5 kg (signalment otherwise unknown) was administered FRONTLINE PLUS SPOT ON CAT (batch S41303AO and expiry OCT 2021, further details unknown) from AUG 2019 for an unknown indication. The animal owner reports that the animal is still infested and unhappy. The animal owner is unhappy after paying money for a product that doesn't work. They are a pensioner and cannot afford to waste money this way. The animal owner asks if it can be updated somehow as the fleas must have become immune to it. The animal owner reports that they treat their animal when they see fleas, only over the summer and started using the product in AUG 2019 when they first noticed fleas on their pet. The animal owner used the product as directed and also used it in SEP 2019. No one in the home is being bitten by fleas, the animal spends time indoors and outdoors and all animals that live in the household or in contact animals have been treated with a flea treatment. The animal owner is seeing many fleas - more than 5 at the same time, the animal is never bathed nor goes swimming, and the animal owner has treated the home with an environmental flea treatment (Indorex), washed the pet's bedding at over 60 degrees and regularly vacuumed all areas that the pet can access.
20-Sep-2019	UAE; 19UK003195; -, United Kingdom	Species: Feline Breed: Feline (unknown) Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	Jul-2019*	31-Jul-2019*	N/A	D-D	As reported by the animal owner, a male feline (signalment otherwise unknown) was given FRONTLINE PLUS SPOT ON CAT (batch and expiry unknown) for the last two months (estimated starting on JUL 2019) by the animal owner as a parasiticide (no further details available). The animal owner reports that they are not very happy with the product. They bought their kitten and he had fleas, they've been using FRONTLINE PLUS and it hasn't helped at all. He is still covered in flea dirt and they've just been through his coat again after his 3rd treatment and they have found 13 fleas. Start date for submission purposes only.
20-Sep-2019	UAE; 19UK003197; -, United Kingdom	Species: Feline Breed: Feline (unknown) Sex: F Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	01-Sep-2019*	N/A	D-D	As reported by the animal owner, a female feline (signalment otherwise unknown) was given FRONTLINE SPOT ON CAT (batch and expiry unknown) monthly by the animal owner for parasite control (no other details available). The animal owner reports that they have come to the end of their tenancy at their rental property and after removing their cat from the property, having given her a dose of FRONTLINE less than 1 month ago, they have been told that the property is infested with fleas. The animal owner has contacted the cattery where her cat is currently staying and they have also informed her that the cat has fleas on her and in her pen. The animal owner has contacted their vet and asked how their cat has got fleas even though that have been using necessary preventing treatments on her. The vet told the animal owner that FRONTLINE does not work and doesn't stop or kill fleas. The animal owner has asked around other cat owners who have said that FRONTLINE does not work on their pet. Start date for submission purposes only.
20-Sep-2019	UAE; 19UK003199;	Species: Canine Breed: Canine	1	1	0	Product used: FIPRONIL	N/A	Sep-2019*	N/A	D-D	As reported by a retail outlet employee via the animal owner, a dog (signalment otherwise unknown), was treated with FRONTLINE

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 294 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00301

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	-; United Kingdom	(unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown				10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Contraindication per label)					PLUS SPOT ON DOGS M (batch number and expiry date unknown), 1 pipette applied to the back of the neck, by the cat's owner on an unknown date. The owner reported to the retail outlet employee that they were still seeing fleas, so believed the product had not worked. The owner went to vet practice who told the owner that FRONTLINE did not work. The owner also mentioned the dog had been in water straight after the application. The vet practice told the owner that FRONTLINE is not water proof, so the dog going in water after application was not great. The owner complained that the product obviously did not work and they were not told that it was not water proof. The vet practice gave the owner a tablet instead to use and would not be using FRONTLINE again. Date of event added for submission purposes only.
17-Sep-2019	UAE; 19UK003200; -; United Kingdom	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: F Sex qualifier: Unknown Age: 12.00 Year(s) Weight: 3.5 kg	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: Home flea Spray; Route: Topical / Cutaneous Was the product used ok?: Yes	N/A	Mar-2019*	N/A	D-D	As reported by the animal owner, Mrs Tibbs a 12 year old, female Domestic Shorthaired cat (the only cat in the household), weighing approximately 3.5 kg, was given FRONTLINE SPOT ON CAT (batch number: S21204BW and expiry date: 01 AUG 2021) at an unknown dose, the last 4 applications were carried out on 15 JAN 2019, 15 JUN 2019, 06 AUG 2019 and 07 SEP 2019, administered by the animal's owner to the back of the neck as instructed. On 17 SEP 2019 the owner wanted to know if it was possible for fleas to become resistant to FRONTLINE. They had been treating their cat with FRONTLINE SPOT ON for years (for approximately 8-10 years) when they saw fleas (but not applied more frequently than once per month), and it had always worked very well. However about 6 months ago (date estimated as MAR 2019), it just suddenly seemed to stop working. The owner was finding many fleas on their cat over the summer (MAY and JUN 2019), sometimes just days after treatment. They followed the instructions well, the cat was confined to areas of the house that are easy to clean (laminated flooring etc.), and combed the cat relatively regularly, so they were fairly sure they were not being reintroduced from within the home. They had not really noticed many fleas around the house, they just seem to be concentrated on the cat (they were seeing more than 5 at any one time). The people in the home were only being bitten occasionally. The cat spent most of its time indoors and in the garden and the cat had not been bathed. The owner had lived in house for more than 10 years. The owner had regularly vacuumed the laminated floors, had washed the bedding regularly and had occasionally used flea spray (assumed to be home flea spray).
20-Sep-2019	UAE; 19UK003202; -; United Kingdom	Species: Canine Breed: Spaniel (Cocker) Sex: U Sex qualifier: Unknown Age: 6.00 Year(s) Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	13-Sep-2019	13-Sep-2019	N/A	D-D	As reported by the animal owner, their 2 Cocker Spaniel dogs, aged 6 years (signalment otherwise unknown) were treated with FRONTLINE PLUS SPOT ON DOGS M (batch number and expiry date unknown), route unknown, administered by the dog's owner on approximately 13 SEP 2019, then again 4 days later on 17 SEP 2019 (as the first treatment had not completely worked). On 20 SEP 2019, 3 days after the second treatment, the owner reported that when they combed the dog's with a flea comb, they were still finding fleas on them. The owner reported that the dog's had experienced a bout of fleas, although the owner had kept their coats short, however, the infestation had got quite bad before they had noticed it.
20-Sep-2019	UAE; 19UK003206;	Species: Feline Breed: Feline	1	1	0	Product used: FIPRONIL	N/A	01-Sep-2019*	1 Day(s)	D-D	As reported by the animal owner, an intact male feline (signalment otherwise unknown) was given FRONTLINE PLUS SPOT ON CAT

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 295 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00302

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	-; United Kingdom	(unknown) Sex: M Sex qualifier: - Age: - Weight: Unknown				10%/S METHOPRENE 12% SPOT ON Other products used: Indorex; Route: unknown Was the product used ok?: No (Treatment / vaccination program not respected)					(batch and expiry unknown) on an unknown date by the animal owner as a parasiticide (no further information available). The animal owner reports that they treated the cat with the product and treated their house with Indorex on the same day (exact date unknown, estimated AUG 2019). After 3 days the cat was scratching again. The animal owner repeated the treatment after 3 weeks, a week later the cat was just as bad. The animal owner treated him again and they have just had him castrated, where the vet told them the cat still had fleas. The animal owner bought 6 pipettes and has used three of them in 2 months. The animal owner has used this product in the past with success and it seems that this batch of FRONTLINE may be substandard or fleas have built up an immunity. Start date for submission purposes only.
21-Sep-2019	UAE; 19UK003207; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: F Sex qualifier: Unknown Age: 18.00 Month(s) Weight: 10 kg*	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: Indorex Spray; Advocate; Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	20-May-2019	11-Aug-2019	N/A	D-D	As reported by the animal owner, Suki, an approximately 18 month old female canine weighing approximately 10 kg (signalment otherwise unknown) was given FRONTLINE PLUS SPOT ON DOG S, batch S61716AL and expiry JUN 2021) by the animal owner topically to the back of the neck, on 20 MAY 2019, 21 JUL 2019 and 20 SEP 2019 for parasite control. The animal owner reports that their dog got fleas 3 weeks after applying FRONTLINE PLUS when it clearly state on the packet that it protects against re infestation for 8 weeks. The dog does not swim and has not been bathed in that time. The animal owner had to wait another 2 weeks with the dog scratching and kept her away from other dogs before she could be given another application to get rid of them. The animal owner treats the dog every 8 weeks and sometimes has a short break from treatment over the winter if it is cold. The animal owner reports that they started using FRONTLINE PLUS for the current flea issue on 21 JUL 2019 and they then treated with Advocate on 16 AUG 2019 to eliminate the fleas. They first noticed fleas on 11 AUG 2019. People in the home are not being bitten, the animal spends time indoors and outdoors, goes to a dog walker or doggy day care and in a second indoor environment. The animal owner reports seeing many fleas - more than 5 at the same time, the animal is bathed very occasionally and only goes in puddles and doesn't swim. The animal owner has treated the home with Virbac Indorex Spray and regularly vacuumed all areas that the pet can access.
21-Sep-2019	UAE; 19UK003208; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	21-Sep-2019	6 Day(s)	D-D	As reported by the animal owner, a male canine (signalment otherwise unknown) was given FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG M, batch and expiry unknown) on 15 SEP 2019 by the animal owner as a parasiticide (no further details available). The animal owner reports that they treated their dog 6 days ago and this morning (21 SEP 2019) they have found fleas on him again.
22-Sep-2019	UAE; 19UK003211; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: M	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE	N/A	01-Sep-2019*	N/A	D-D	As reported by the animal owner, a male crossbreed canine weighing 10 kg (signalment otherwise unknown) was given FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG M, batch and expiry unknown) by the animal owner as a

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 296 of 867

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00303

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: Unknown Age: - Weight: 10 kg				9% SPOT ON Other products used: FRONTLINE PETCARE HOME AND ENVIRONMENT FLEA SPRAY; Route: unknown Was the product used ok?: Unknown to Company					parasiticide (no further details available). The animal owner reports that they found fleas on the dog so bathed and combed him, and when he was dry they used FRONTLINE PLUS. However 7 days later he was still scratching so the animal owner put him in the bath and several fleas came off his coat. Five days ago (17 SEP 2019) the animal owner also purchased our home spray (assumed FRONTLINE PETCARE HOMEWARD HOUSEHOLD FLEA SPRAY, batch and expiry date unknown). The animal owner hoovered all the house, washed their own bedding and the dog's bedding and toys and dried them in the tumble drier. The animal owner sprayed all the rooms in the house, closed all the doors and left it over night. They then vigorously hoovered the next day including the corners and under the furniture. They hoovered once or twice each day after. However, they are still seeing remnants. The animal owner added that they used FRONTLINE PETCARE HOMEGARD HOUSEHOLD FLEA SPRAY 6 days ago, the instructions have been followed, and they are concerned that they are still seeing fleas in their home and on their dog. They would hope that using both the products that they would not still see fleas either in their home environment or their dog. Start date for submission purposes only.
23-Sep-2019	UAE; 19UK003212; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: F Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	09-Sep-2019*	0 Day(s)	D-D	As reported by the animal owner, a female canine (signalment otherwise unknown) was given FRONTLINE (assumed FRONTLINE SPOT ON DOG M, batch and expiry unknown) on 09 SEP 2019 by the animal owner (no further details available). The animal owner reports that the dog was at the groomers the day after application so they think it has affected the application. They have still got fleas. Start date for submission purposes only.
23-Sep-2019	UAE; 19UK003214; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: 19.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a 19 year old feline (signalment otherwise unknown) was administered FRONTLINE (assumed FRONTLINE SPOT ON CAT, batch and expiry unknown, details unknown) at a dose of two pipettes for fleas. The animal owner reports that they recently purchased FRONTLINE for their cat. The treatment after two pipettes has not been effective. They have now washed their cat and manually removed the fleas. The animal owner added that they have never had problems with the product before. They have used cheaper products and this, which is most expensive. The animal owner has checked with their vets and they have advised them that FRONTLINE is not worthy and not to buy the products until the animal is checked. The animal owner has now used Bob Martin Shampoo and treatment and can see endless results. The animal owner is fully aware of how the treatments work, they are just mortified that the product has not worked. Start date added for submission purposes only.
23-Sep-2019	UAE; 19UK003216; -; United Kingdom	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: M Sex qualifier: Neutered Age: 16.00	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous	Jun-2019*	Jun-2019*	N/A	D-D	As reported by the animal owner, Sooty, a 16 to 18 month old male neutered Domestic Shorthair feline, of unknown weight and in good condition, was administered FRONTLINE SPOT ON CAT (batch and expiry unknown) topically to an unknown site, by the animal owner, at a dose of 1 pipette monthly from JUN 2019 to SEP 2019 as recommended by a friend. The animal owner reports that they have always kept cats and have always used rubber flea repellent collars and never had a major flea problem. A friend

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 297 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00304

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Month(s) Weight: Unknown				Was the product used ok?: Yes					recommended FRONTLINE SPOT ON for their 16 month old male cat and so they purchased 6 pipettes online. The animal owner has said that the product was utter rubbish and doesn't work at all. They now have a home infestation and they are being bitten. The cat is scratching a lot and also had a tick. The animal owner has spent a fortune on carpet sprays (product unknown) but the vet has advised not to use the spray and to use foggers for the home instead. The animal owner is going to see the vet for alternative treatment for the animal and is planning to go back to the repellent collars. The animal owner has spent a fortune on a ton of different products and is in the process of ripping all the carpets up. The animal owner also said that the issue is affecting their mental health and their illnesses. The animal owner is convinced that the product is the reason that they have a home infestation. On 27 SEP 2019 the animal owner added that FRONTLINE has left their cat and house infested for the last 6 weeks roughly and they have been trying to get rid of them. Their cat Sooty is chronically itching, and the animal owner is covered in a terrible rash. They have spent so much money buying sprays and potions to rid the house, and they have spent more money again buying a six pack. The animal owner has bought a Johnsons smoke bomb but their nurse is not happy with the owner letting it off as they have a serious lung condition (COPD). The carpets are in the middle of being taken up and
23-Sep-2019	UAE; 19UK003221; -; United Kingdom	Species: Feline Breed: Siamese Sex: M Sex qualifier: Neutered Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	Jun-2019*	Aug-2019*	N/A	D-D	As reported by the animal owner, a male neutered Siamese feline (signalment otherwise unknown) was administered FRONTLINE PLUS SPOT ON CAT (batch S41303AW expiry unknown) from 3 months ago (estimated JUN 2019) at an unknown dose monthly by the animal owner for part of their monthly treatment. The animal owner has been using the product for years but was suspicious of this particular batch as they believe that it suddenly isn't working. The animal owner wants to check that it is not falsified. The animal owner reported that the first two pipettes seemed to work fine and the third one they are suspicious about as they have seen fleas recently. Only a few fleas are being seen and the animal owner is not being bitten. The animal owner has also mentioned that they have seen wild rabbits in the garden.
24-Sep-2019	UAE; 19UK003237; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	12	12	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	N/A	24-Sep-2019	2 Day(s)	D-D	As reported by the animal owner, 12 felines, signalment otherwise unknown, were administered FRONTLINE SPOT ON CAT (batch S21715AL and expiry OCT 2021) two days ago (22 SEP 2019) by the animal owner, at a dose of 1 pipette per animal for an unknown indication. The animal owner reports that today they have brushed them all and every single cat still has fleas. They are totally disgusted in spending money that they didn't have and to find nothing has changed. The animal owner is disabled and only gets benefits as they do not work. They borrowed the money to treat their cats and sadly they are all still the same. The animal owner added that they flead all the cats last Sunday when they received the product. They flea their cats every month and worm them. The last four treatments were started in JUN 2019. One of their grandchildren has been bitten on the ankle and the animal owner would say that there are at least 10 to 15 fleas on each cat every time they put the flea comb through them. The animal owner combs them all every single day. The animal owner has also been informed that the company already knows that the product doesn't work hence the new one that they now have called BROADLINE.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 298 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00305

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											The animal owner does the home every day and use a brilliant product that removes eggs, fleas etc. They use Indorex which they use each month. The animal owner has had cats over 50 years and they know what they are doing and they know what works and what doesn't work. Quite a few of the animal owner's friends have said that the product does not kill fleas.
17-Sep-2019	UAE; 19UK003245; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: 40 kg	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	N/A	24-Sep-2019	N/A	D-D	As reported by the animal owner, a dog (signalment otherwise unknown), was treated with FRONTLINE SPOT ON DOG 20 – 40 kg (assumed to be FRONTLINE SPOT ON DOG L) batch number and expiry date unknown, route and frequency unknown, administered by the dog's owner on an unknown date. The owner reported on 24 SEP 2019 that the product did not work, it did not kill any fleas. The owner could also not put any other type of solution on to the animal for a month.
25-Sep-2019	UAE; 19UK003246; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: No (Overdose)	N/A	25-Sep-2019	N/A	D-D	As reported by the animal owner, their 2 cats (signalment otherwise unknown) were treated with FRONTLINE PLUS SPOT ON CATS (batch number and expiry date unknown), route and frequency unknown, administered by the cat's owner, 1 pipette used to treat each cat on two occasions (2 weeks apart), as the cats were still scratching and the fleas were multiplying. The owner reported on 25 Sep 2019 that the product did not kill the fleas and they were very disappointed with the product.
24-Sep-2019	UAE; 19UK003255; Somerset; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, approximately two canines (signalment otherwise unknown) were administered FRONTLINE (assumed FRONTLINE SPOT ON DOG M, batch S62720BW expiry SEP 2021, details unknown) for an unknown indication. The animal owner reports that they are disappointed with FRONTLINE. They have used it on their dogs for many years without any problems - this year being the exception. Despite using it correctly, the animals are being attacked by fleas every day and when grooming they find more and more on their coats. Start date added for submission purposes only.
24-Sep-2019	UAE; 19UK003256; -; United Kingdom	Species: Canine Breed: Dachshund Sex: M Sex qualifier: Unknown Age: 1.00 Year(s) Weight: 7 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	24-Sep-2019	23 Day(s)	D-D	As reported by the animal owner, a 1 year old male Dachshund canine weighing 7 kg (signalment otherwise unknown) (details unknown) by the animal owner on 01 SEP 2019 for fleas. After a few days he was free of fleas. The animal owner has it down on the calendar to do the next treatment exactly 4 weeks from 01 SEP 2019, however today (24 SEP 2019) they have found live fleas on him again. The animal owner is horrified as they thought they had seen their last flea.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 299 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

v1.2

ED_005739D_00014390-00306

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
25-Sep-2019	UAE; 19UK003258; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	2016*	Sep-2019*	0 Day(s)	D-D	As reported by the animal owner, two felines (signalment otherwise unknown) were administered FRONTLINE SPOT ON CAT (batch and expiry unknown, details unknown) by the animal owner from at least 3 years ago (estimated 2016) for an unknown indication. The animal owner reports that they recently treated their cats in JUN 2019, AUG 2019 and SEP 2019. Just over three weeks ago the animal owner examined one of their cats who was losing his fur to find that he was full of fleas and flea dirt. The cats have access to the whole house - and they treated them regularly with FRONTLINE - precisely so that they would not have to worry about fleas. The animal owner took the cats to the vets for treatment and they contacted three different vets who all informed the animal owner in no uncertain terms that FRONTLINE no longer works as fleas have built up an immunity to it. For the past three weeks the animal owner has been vacuuming, spraying, washing bedding and clothes and cleaning every day. Their grandson and the animal owner have several nasty flea bites on their legs. The animal owner has had to strip all the beds, wash all the bedding and clean the mattresses. The whole experience has been horrible for all household members and the cats, and it is only the last four days that they feel that the house is clear and they have suffered no more bites. Sadly the cats are now banned from having full access to the house. They can only have access to the kitchen (where there is no carpet) and the rear garden. They are also wary of the animal owners because of being bundled into a cat carrier for vet visits (both are nervous cats) and because they were constantly having to check their fur, wipe their fur with a damp cloth, spray them and use a tooth comb. The animal owner is extremely annoyed and upset that they find themselves in this position and disappointed that FRONTLINE did not offer protection. FRONTLINE is expensive to buy and it doesn't even work. The animal owner will never
18-Sep-2019	UAE; 19UK003261; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a feline (signalment otherwise unknown) was administered FRONTLINE PLUS SPOT ON CAT (batch and expiry unknown, details unknown) for an unknown indication. The animal owner reports that the animal had a sore, red patch on the back of the neck after FRONTLINE PLUS (assumed at application site). Start date added for submission purposes only.
26-Sep-2019	UAE; 19UK003263; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used	Mar-2019*	Mar-2019*	N/A	D-D	As reported by the animal owner, approximately 2 felines (signalment otherwise unknown) were administered FRONTLINE PLUS SPOT ON CAT (batch and expiry unknown, details unknown) by the animal owner, at a dose of 1 dose every 4 weeks from 6 months ago (MAR 2019) for an unknown indication. The animal owner reports that they would like advice on why FRONTLINE PLUS isn't working for their cats. They have been treating the cats every four weeks for the last six months as well as using fog bombs on the house and the flea problem doesn't seem to be getting any better. The animal owner has completely lost faith in the product. The animal owners are also getting bitten on a daily

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 300 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00307

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						ok?: Unknown to Company					basis and they have also had to have steroid treatment for one of the cats as he has an allergy to fleas.
26-Sep-2019	UAE; 19UK003265; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: F Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, Mittens, a female feline (signalment otherwise unknown) was administered FRONTLINE SPOT ON CAT (batch and expiry unknown, details unknown) for flea treatment. The animal owner reports that the animal now has small lumps where it was applied. They have always used FRONTLINE. Start date added for submission purposes only.
26-Sep-2019	UAE; 19UK003267; -; United Kingdom	Species: Canine Breed: Spaniel (Cocker) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, two Cocker Spaniel canines (signalment otherwise unknown) were administered FRONTLINE PLUS SPOT ON DOG M (batch S62720BW, expiry SEP 2021) (details unknown) by the animal owner for an unknown indication. To the animal owner's disgust they both have fleas. They have now had to go to their vets and purchase prescription flea treatments for the animals and the house. Start date added for submission purposes only.
26-Sep-2019	UAE; 19UK003271; Gloucestershire; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	Apr-2019*	Jul-2019*	0 Day(s)	D-D	As reported by a retailer, a canine (signalment otherwise unknown) was given FRONTLINE SPOT ON (estimated FRONTLINE SPOT ON DOG M, batch number 820221AL expiry date JAN 2021) since APR 2019, given by the animal owner (no further details available). The retailer reports that the animal owner purchased the product in APR 2019 and has always been treating their dog with this flea treatment. In the past 2 months (estimated starting JUL 2019) the dog has been infested with fleas. They have had to go to the vets and pay for a more effective treatment.
27-Sep-2019	UAE; 19UK003272; -; United Kingdom	Species: Feline Breed: Calico Sex: M Sex qualifier: - Age: 1.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	30-Aug-2019	Sep-2019*	N/A	D-D	As reported by the animal owner, Ace an intact male Calico feline aged 1 year and of unknown weight, and in good condition, was given FRONTLINE SPOT ON CAT (batch number S20306AW expiry date FEB 2021) on 30 AUG 2019 topically by the animal owner at an unknown dose for an unknown reason. The animal owner reports that they also used foggers, boric acid and spray for the house on the same day. Another FRONTLINE SPOT ON treatment was given on 13 SEP 2019. The animal owner is using a flea comb and drowning fleas. People in the house are being bitten by fleas. Start date for submission purposes only.
27-Sep-2019	UAE; 19UK003280; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: F Sex qualifier:	2	2	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other	N/A	2019*	N/A	D-D	As reported by the animal owner, Boo, a 7 year old female feline weighing 2 kg, and Luna a 6 month old female feline weighing 1 kg, were administered FRONTLINE SPOT ON CAT (batch S41306AW expiry OCT 2021) topically (details unknown) by the animal owner for an unknown indication. The animal owner reports

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 301 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00308

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Unknown Age: 6.00 Month(s) Weight: 1 - 2 kg				products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company					that they think that the product is fake. They have searched online to find out what the box should have on it etc and if it is fake. The animal owner mentioned hitchhiker fleas and that they are not being bitten at home. A flea comb and powder is being used. Start date added for submission purposes only.
27-Sep-2019	UAE; 19UK003283; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, a dog (signalment otherwise unknown), was treated with FRONTLINE (estimated as FRONTLINE SPOT ON DOG) batch number and expiry date unknown, route and frequency unknown, used for 2 months, on unknown dates. On 27 SEP 2019 the owner reported that they were still finding pregnant fleas and flea poo on the dog. The owner vacuumed every other day and had treated the floors, bedding and all furnishings.
27-Sep-2019	UAE; 19UK003287; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, two canines (signalment otherwise unknown) were administered FRONTLINE (assumed FRONTLINE SPOT ON DOG M, batch and expiry unknown, details unknown) for an unknown indication. The animal owner reports that they bought the company's product for their 2 dogs and they still have fleas. Start date added for submission purposes only.
27-Sep-2019	UAE; 19UK003289; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	2019*	N/A	D-D	As reported by the animal owner, approximately two canines (signalment otherwise unknown) were administered FRONTLINE (assumed FRONTLINE SPOT ON DOG M, batch and expiry unknown, details unknown) by the animal owner for an unknown indication. The animal owner reports that they have been a FRONTLINE customer for around 10 years and have never had any problems until lately. They bought some flea and tick treatment, which they use regularly and religiously. The animal owner says that after around 1 week of treatment the dogs started biting profusely. They checked the areas and couldn't see anything, so they took them to the vet the following day. The vet then checked said areas and found fleas, not just one but a few. The vet asked the animal owners what they use and they told them FRONTLINE, and the vet told them they have had a vast number of people with the same problem and all had used this product. The animal owner got home and found an untold amount of people saying the same thing online. The animal owner has great disappointment and anger as they had to flea bomb their whole house and chuck the beds which were not cheap at all. Start date added for submission purposes only.
28-Sep-2019	UAE; 19UK003290; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products	Sep-2019*	Sep-2019*	0 Day(s)	D-D	As reported by the animal owner, two felines (signalment otherwise unknown) were administered FRONTLINE PLUS SPOT ON CAT (batch and expiry unknown) (details unknown) topically by the animal owner at a dose of 3 doses in a week for an unknown indication. The animal owner reports that they ordered FRONTLINE PLUS for their two cats last week, and they have had

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 302 of 867

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00309

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: - Weight: Unknown				used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Overdose)					to put two treatments of it on them since, with still no luck. They just seem to have multiplied in fleas and the animal owner has even been spraying the house, which has helped, but not if the cats still have them. The animal owner will not be buying FRONTLINE again and will be waiting a while before they can put any more flea stuff on them and so will have to see them suffer until they can do that.
28-Sep-2019	UAE; 19UK003294; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	28-Sep-2019	2 Day(s)	D-D	As reported by the animal owner, a dog (signalment otherwise unknown), was treated with FRONTLINE SPOT ON (estimated as FRONTLINE SPOT ON DOG M) batch number and expiry date unknown, route and frequency unknown, administered by the dog's owner on 26 SEP 2019 but the owner reported on 28 SEP 2019 that the fleas were still present and driving them all crazy.
30-Sep-2019	UAE; 19UK003295; -; United Kingdom	Species: Canine Breed: Spaniel (English Springer) Sex: M Sex qualifier: Unknown Age: 13.00 Year(s) Weight: 21 kg	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	24-Sep-2019*	N/A	D-D	As reported by the animal owner, Flynn, a 13 year old male Springer Spaniel dog weighing 21 kg (signalment otherwise unknown), was treated with FRONTLINE COMBO SPOT ON DOGS L (batch number S60109BR and expiry date DEC 2020) route unknown, at a dose of 1 dose every 8 weeks for years, administered by the dog's owner for fleas. On 30 Sep 2019 the owner reported that the dog has had a flea infestation. The owner has used the FRONTLINE brand effectively for many years. The vet advised the owner to use another treatment due to resistance to the FRONTLINE flea treatment. The animal owner added that the animal has been using FRONTLINE for years and is protected in accordance with the company's advice and instructions. Last week the animal had a bad flea infestation, the first since he has been on FRONTLINE and he was covered in fleas and flea dirt even though he had had his regular flea treatment. The animal owner had given him his treatment on 18 AUG 2019 and then a few days before 27 SEP 2019 the fleas and flea dirt were noticed and they gave the animal another dose. The last four dates that the animal owner applied the product were 27 SEP 2019, 18 AUG 2019, 18 JUN 2019 and 18 APR 2019. The animal owner applies the product in accordance with company instructions and people in the home are not being bitten. The animal spends time indoors and outdoors and in a second indoor environment, all animals in the household and in contact animals have been treated with a flea product, the animal owner is seeing many fleas - more than 5 at the same time, and the animal is bathed or goes swimming no more than once a week. The animal owner has also treated the home with an environmental flea treatment and regularly vacuumed all areas that the pet can access. The animal owner states that after many years of using FRONTLINE product and being very satisfied with the outcome they must now write to the company. They have been sold the product but it had no effect this time in controlling a
30-Sep-2019	UAE; 19UK003297; -; United Kingdom	Species: Feline Breed: Domestic Shorthair (Crossbreed)	3	3	0	Product used: FIPRONIL 10%/S METHOPRENE	N/A	2019*	N/A	D-D	As reported by the animal owner, Keith, a 7 year old male weighing 2.5 kg, Luna, a 14 month old female weighing 3.5 kg and Nacho, a 3 year old male weighing 2.2 kg, all neutered Domestic Short Hair felines, were administered FRONTLINE PLUS SPOT ON CAT

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 303 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00310

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex: X Sex qualifier: Neutered Age: 1.17 Year(s) Weight: 2.2 - 3.5 kg				12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes					(batch S41113AW expiry AUG 2021, details unknown) topically to an unknown site, every 30 days, by the animal owner for an unknown indication. The animal owner reports that they have hitchhiker fleas and they are using flea bombs and a flea spray. Start date added for submission purposes only.
30-Sep-2019	UAE; 19UK003298; -, United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	Jun-2019*	Jun-2019*	N/A	D-D	As reported by the animal owner, two felines (signalment otherwise unknown) were administered FRONTLINE PLUS SPOT ON CAT (batch and expiry unknown) (details unknown) by the animal owner for three months (estimated to start JUN 2019) for an unknown indication. The animal owner reports that this is the supply that you purchase from the animal medication site and it has not made any difference. If anything their scratching has worsened, so much so that one of the cats is getting bald patches.
25-Sep-2019	UAE; 19UK003299; Essex; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: 10 - 20 kg	4	4	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: Environmental flea treatment; Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	Aug-2019*	Aug-2019*	N/A	D-D	As reported by the owner, via a distributor, 4 dogs (weighing between 10 and 20 kg), signalment otherwise unknown, were treated with FRONTLINE PLUS (assumed to be FRONTLINE PLUS SPOT ON DOGS M) batch number: S62703AW and expiry date: unknown, at a dose of 1 pipette, applied topically, every 4 weeks, administered by the animal's owner, as they had seen fleas. The FRONTLINE PLUS was originally purchased in AUG 2019 as the owner was seeing significant flea activity on the dogs. Environmental flea treatment was also purchased. A week later on 24 AUG 2019, the owner contacted the distributor to report that they were still seeing fleas. The customer contacted the distributor again on 25 SEP 2019 to say they still had the same issue and that they had been to see the vet who had told the owner FRONTLINE does not work. The owner had also had their house professionally treated against fleas twice and her pest controller had reported that they had never had to treat a house twice.
30-Sep-2019	UAE; 19UK003300; -, United Kingdom	Species: Canine Breed: Canine (unknown) Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL SPOT ON DOG Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	23-Sep-2019*	2 Week(s)	D-D	As reported by the animal owner, a male canine, signalment otherwise unknown, was administered FRONTLINE (assumed FRONTLINE SPOT ON DOG M) (batch and expiry unknown) (details unknown) by the animal owner three weeks ago (estimated 09 SEP 2019) for an unknown indication. The animal owner used the product three weeks ago on their boy and he has started to scratch badly again this week. The council fumigated their home 2 weeks ago and they ask what they can do now.
28-Sep-2019	UAE; 19UK003302; -, United Kingdom	Species: Canine Breed: Retriever Labrador Sex: U Sex qualifier: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products	N/A	28-Sep-2019	N/A	D-D	As reported by the animal owner, a Labrador dog weighing 23 kg (signalment otherwise unknown), was treated with FRONTLINE PLUS SPOT ON DOGS L (batch number and expiry date unknown), applied as per the instructions, administered by the dog's owner on 2 occasions, 2 weeks apart. On 28 SEP 2019 the owner reported that despite the 2 doses given the dog still had

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 304 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00311

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: - Weight: 23 kg				used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)					fleas. The owner also reported that the vet had now confirmed that the dog still had fleas and the dog was being treated appropriately. The animal owner added that they have no grass in their rear garden and the animal has no access to any grassed areas. They have treated their dog twice with the product and, as confirmed by their vet, it has made no difference. The animal owner fully understands how the product works but clearly it is not effective on their dog.
30-Sep-2019	UAE; 19UK003303; -; United Kingdom	Species: Feline Breed: Bengal Sex: F Sex qualifier: Unknown Age: 8.00 Year(s) Weight: 3.5 kg	1	1	0	Product used: FIPRONIL SPOT ON CAT Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	N/A	09-Sep-2019*	0 Day(s)	D-D	As reported by the animal owner, Cheetah, an 8 year old female Bengal feline weighing 3.5 kg and in good condition, was administered FRONTLINE SPOT ON CAT (batch S20306AW expiry FEB 2021) (details unknown) topically by the animal owner, on 09 SEP 2019 for an unknown indication. The animal owner reports that they first applied the product 3 weeks ago and the animal was on a different product previously. The animal owner wanted to report that fleas were still being seen and the animal has come out in scabs caused by the product. The animal owners are not being bitten in the home. There is a dog in the home that receives Bob Martin. MAH comment: This case is classified as both 'SLEE' and 'Adverse Reaction' but due to a limitation of the database it might be that only the highest hierarchical product problem type, which is 'Adverse Reaction', has been transmitted.
28-Sep-2019	UAE; 19UK003306; -; United Kingdom	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	28-Sep-2019	N/A	D-D	As reported by the animal owner, their dogs, number of animals estimated as 2 (signalment otherwise unknown) were treated with FRONTLINE ADVANTAGE (estimated to be FRONTLINE PLUS SPOT ON DOG M) batch number and expiry date unknown, route and frequency unknown, administered by the dog's owner on an unknown date, so the animals did not get fleas. On 28 SEP 2019 the owner reported that upon using the product, the animal's got fleas and the product did not seem to be working.
28-Sep-2019	UAE; 19UK003307; -; United Kingdom	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	N/A	28-Sep-2019	N/A	D-D	As reported by the animal owner, their cats, number of animals estimated as 2 (signalment otherwise unknown) were treated with FRONTLINE ADVANTAGE (estimated to be FRONTLINE PLUS SPOT ON CAT) batch number and expiry date unknown, route and frequency unknown, administered by the cat's owner on an unknown date, so the animals did not get fleas. On 28 SEP 2019 the owner reported that upon using the product, the animal's got fleas and the product did not seem to be working.
18-Sep-2019	UAE; 19UK003475; -; United Kingdom	Species: Canine Breed: Canine (unknown)	1	1	0	Product used: FIPRONIL SPOT ON DOG	N/A	01-Sep-2019*	N/A	N/A	As reported by the animal owner, a canine (signalment otherwise unknown, assumed 1 animal only) was given FRONTLINE (assumed FRONTLINE SPOT ON DOG M, batch and expiry

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 305 of 867

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00312

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex: U Sex qualifier: Unknown Age: - Weight: Unknown				Other products used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON; FRONTLINE PETCARE HOME AND ENVIRONMENT FLEA SPRAY; Route: unknown Was the product used ok?: Unknown to Company					unknown) and FRONTLINE PLUS (assumed FRONTLINE PLUS SPOT ON DOG M, batch and expiry unknown) by the animal owner (no further information available). The animal owner reports that our products do not work, our flea spray claims to kill fleas in the home (assumed FRONTLINE PETCARE HOMEGARD HOUSEHOLD FLEA SPRAY, batch and expiry unknown) for 12 months, it does not even kill them for a day. The animal owner also states that FRONTLINE and FRONTLINE PLUS does not kill fleas at all and they are not the only person who knows our products are no good. Start date for submission purposes only.
25-Jul-2019	UAE; 19US025915; FL; U.S.A	Species: Canine Breed: Boxer Sex: M Sex qualifier: Neutered Age: - Weight: 50 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	19-Apr-2019	25-Jul-2019	5 Week(s) 1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 May 2019 the pet owner reported the following event for an unknown 60 pound male boxer coonhound (Black and Tan) mix. All other signalments are unknown. *16 Apr 2019: The owner noticed an unknown amount of fleas on the dog. 19 Apr 2019: The owner applied 1 vial of FRONTLINE PLUS DOG 45-88 LBS (S60104AR) to the skin between the shoulder blades for the first time. 20 Apr 2019: The owner continued to see at least 3 fleas on the dog at all times. The dog began biting at his back, feet and paws because of irritation to the fleas. 10 May 2019: The dog presented to the vet clinic. It is unknown if the dog has received any treatments. The dog has a history of skin issues. There is 1 other pet in the home sharing the same product with case 19US026013. The owner feels itchy inside of the home but has not seen any flea activity. The dog has access to a concrete porch and a fenced in grassy yard. The dog will not be continuing on FRONTLINE PLUS. The owner has used FRONTLINE brand products on other dogs in the past and never seen fleas. No further medical information expected. UPDATE 23 May 2019: Case changed to an inquiry due to preexisting fleas and only one dose administered. UPDATE 25 Jul 2019: Per pet owner, Teddy is a 50 pound, neutered male, Coonhound/ Boxer cross. 19 May 2019* and 19 Jun 2019*: Applied FRONTLINE PLUS DOG and is continuing to see fleas. No further medical information expected.
25-Jul-2019	UAE; 19US026013; FL; U.S.A	Species: Canine Breed: Spaniel (Cocker) Sex: F Sex qualifier: Neutered Age: 10.00 Year(s) Weight: 50 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	19-Apr-2019	25-Jul-2019	5 Week(s) 1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 May 2019 the pet owner reported the following event for an unknown 50 pound female spaniel (Cocker). All other signalments are unknown. *16 Apr 2019: The owner noticed an unknown amount of fleas on the dog. 19 Apr 2019: The owner applied 1 vial of FRONTLINE PLUS DOG 45-88 LBS (S60104AR) to the skin between the shoulder blades for the first time. 20 Apr 2019: The owner continued to see an unknown amount of fleas per day. The dog does occasionally chew like fleas are biting. There is 1 other pet in the home sharing the same product with case 19US025915. The owner feels itchy inside of the home but

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 306 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

v1.2

ED_005739D_00014390-00313

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						ok?: Yes					has not seen any flea activity. The dog has access to a concrete porch and a fenced in grassy yard. The owner has used FRONTLINE brand products on other dogs in the past and never seen fleas. No further medical information expected. UPDATE 23 May 2019: Case changed to an inquiry due to preexisting fleas and only one dose administered. UPDATE 25 Jul 2019: Per pet owner, Honey is a 10 year old spayed female Cocker Spaniel. 19 May 2019* and 19 Jun 2019*: Applied FRONTLINE PLUS DOG and is continuing to see fleas. No further medical information expected.
23-Jul-2019	UAE; 19US026226; IN; U.S.A	Species: Canine Breed: Shih Tzu Sex: F Sex qualifier: Neutered Age: 11.00 Year(s) Weight: 15 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: unknown oatmeal shampoo; Route: Topical / Cutaneous Was the product used ok?: Yes	10-May-2019	23-Jul-2019	10 Week(s) 4 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 13 May 2019, the owner reported the following event for Missy, an 11 year old, 15 pound, spayed female Shih Tzu. History: The dog had fleas for an unknown length of time. 10 May 2019: The dog had fleas and one vial of FRONTLINE PLUS DOG 5-22 LBS (S61006AL) was topically applied to the skin between the shoulder for the first time. The owner is still finding 2-3 fleas at a time on the dog. The dog is exposed to grass for short potty breaks. The dog is bathed once every 2 weeks with an oatmeal shampoo. There are no fleas in the home. No further information available. UPDATE 24 May 2019: Case changed to an inquiry due to preexisting fleas and only one dose administered. UPDATE 17 Jun 2019: The animal owner states that she is still seeing unknown number of fleas on the canine. No further information provided none expected. UPDATE 23 Jul 2019: The pet owner called to report the following: 10 Jun 2019: The monthly dose was applied directly to the skin between the shoulders. Fleas were seen prior to product application. 10 Jul 2019: The monthly dose was applied directly to the skin between the shoulders. Fleas were seen prior to product application. 23 Jul 2019: The pet owner is still noticing fleas. No further medical information expected.
01-Jul-2019	UAE; 19US034584; IL; U.S.A	Species: Feline Breed: Feline various breeds Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	10-Jun-2019	17-Jun-2019*	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 17 Jun 2019, the pet owner reported the following event for 2 felines with unknown signalment. 10 Jun 2019: The cats began receiving FRONTLINE PLUS FOR CATS (lot unknown) every 3 weeks with a 3 pack purchased from Amazon on an unknown date. Fleas were seen on the cats prior to product application. 30 Apr 2019*: A dose was applied to both cats on the skin between the shoulders. 21 May 2019*: A dose was applied to both cats on the skin between the shoulders. 10 Jun 2019: A dose was applied to both cats on the skin between the shoulders. 17 Jun 2019*: The owner noticed a severe amount of fleas on both cats. The cats do live on a large property in the country, and the cats are indoor/outdoor. It is unknown if the cats presented to the veterinary clinic. The condition of both cats is ongoing. There are a total of 2 canines and 15 felines in the household. There are two related cases, see 19US035353 and 19US035376. No further medical information expected. UPDATE 28 JUN 2019: Case updated to inquiry due to treatment

N/A signifies the information for this field is either not available or not applicable

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

Report printed on 25-Oct-2019 at 8:39:59PM

*indicates Approximate date or weight

Page 307 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00314

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											program not respected.
14-Aug-2019	UAE; 19US035306; OK; U.S.A	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: F Sex qualifier: Neutered Age: 1.00 Year(s) Weight: 8 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: Capstar; Route: Topical / Cutaneous Was the product used ok?: Yes	16-May-2019	17-May-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 14 Aug 2019 a pet owner reported the following event for Piper, a 8 pound, 1 year old*, spayed female Domestic Shorthair. 16 May 2019, 16 Jun 2019, 16 Jul 2019, and 13 Aug 2019: Owner applied FRONTLINE PLUS CATS (\$41003AW) to the skin on the animal's neck. 15 Jun 2019* and 15 Jul 2019*: Owner administered Capstar. Cat is continuing to scratch from fleas and owner is seeing 2 to 4 live fleas on the cat's face and chin and this has been occurring since the first use 16 May 2019. Owner had found dead fleas in the home and had a live flea jump on her this morning. A professional exterminator has come out twice and treated the home, once in May 2019* and Jun 2019* and the owner has treated the home with salt and baking soda twice at unknown dates. There are not other animals in the home. Piper does not go outside, but owner reports there are a number of stray cats in her yard. No further medical information expected.
08-Jul-2019	UAE; 19US035550; MI; U.S.A	Species: Feline Breed: Feline (unknown) Sex: M Sex qualifier: Neutered Age: 1.00 Year(s) Weight: 12 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: unknown manufacturer's flea control product; Dawn dish detergent; unknown flea shampoo; Route: Topical / Cutaneous Was the product used ok?: Yes	04-Mar-2019*	04-Jun-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 19 Jun 2019, the pet owner reported the following event for 2 cats, Tiggs, a male neutered, 1 years old, Feline mixed/ various breeds, other signalment unknown, and Smudge, a male neutered, 1 year old, feline mixed/various breeds, other signalment unknown. 4 Apr 2019-4 June 2019: The pet owner first noticed 5-15 fleas on the cats. The pet owner applied one dose of FRONTLINE PLUS CATS (\$40717AW) topically to skin between the shoulder blades of the cats on monthly basis. 5 Jun 2019: The pet owner continued to see 5-15 fleas on the cats. The cats were in good health at time of application. The cats were not presented to veterinarian. The home environment has not been treated by pet owner. The pet owner has seen fleas in the home. The cats have no history of skin problems or any other issues with topical treatments. The cats have not had flea problem before in the past. The cats have not received any other medications or topical treatments. The cats are indoors only. The current status of the cats are unknown. No further medical information. UPDATE 01 JUL 2019: Case updated to inquiry due to treatment program not respected. UPDATE 8 Jul 2019: Per the pet owner, Tiggs weighs 12 pounds*. Unknown dates: Over the winter, the pet owner and her partner began finding an unknown number of fleas on Tiggs, on themselves, and throughout their home. An unknown time after noticing fleas on the feline, the reporter began bathing him with Dawn dish detergent, pro re nata (PRN), on unknown dates via unknown frequency over the next 2 to 3 months. She also treated the home for the same duration. Feb 2019*: An unknown brand/manufacturer's flea control product was administered. The volume, route, and location of administration is unknown; however, the reporter continued to find fleas on Tiggs, on her person, and throughout the home for the 30 days following product application. Mar 2019 (unknown dates): Two vials of FRONTLINE PLUS CATS
12-Sep-2019	UAE; 19US036591; MS; U.S.A	Species: Feline Breed: Feline (unknown)	2	2	0	Product used: FIPRONIL 10%/S	07-Aug-2019	08-Aug-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Jun 2019, the owner reported the following event for 2 felines with unknown signalment. 1 May 2019: The owner reported seeing fleas on the pets.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 308 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00315

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex: U Sex qualifier: Unknown Age: - Weight: Unknown				METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes					6 Jun 2019: The first dose of FRONTLINE PLUS CATS (S41003AW) was applied topically in between the shoulder blades. 24 Jun 2019: The owner reports seeing a large amount of fleas on the cats. The felines are indoor cats. This was the cats first time receiving the product. She does treat year round with an unknown flea and tick product. There are 4 other dogs in the home that are also being treated with FRONTLINE PLUS (Please see case 19US036598). No further information at this time. UPDATE 3 JUL 2019: Case updated to Inquiry due to treatment program note respected. UPDATE: On 23 Jul 2019, the animal owner reported the following: 06 Jul 2019: The second dose of FRONTLINE PLUS CATS one pipette per feline was applied topically between the shoulders. 07 Jul 2019: The owner reports seeing a large amount of fleas on both of the pets. They have not presented to the veterinary clinic. No additional treatments have been initiated. Their current condition is ongoing. No further medical information expected. UPDATE 23 JUL 2019: Case remains an Inquiry due to treatment program not respected. UPDATE: 12 Sep 2019: As reported by the pet owner, on 07 Aug 2019 The third dose of FRONTLINE PLUS CATS one pipette per feline was applied topically between the shoulders. 08 Aug 2019: The cats still have an unknown amount of fleas. Their current condition is unknown. No further medical information expected.
12-Sep-2019	UAE; 19US036598; MS; U.S.A	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	4	4	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	06-Jun-2019	08-Aug-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 24 Jun 2019, the owner reported the following event for 4 canines with unknown signalment. 1 May 2019: The owner reported seeing fleas on the pets. 6 Jun 2019: The first dose of FRONTLINE PLUS DOG (product unsubstantiated) (S41003AW)(invalid) was applied topically in between the shoulder blades. 24 Jun 2019: The owner reports seeing a large amount of fleas on the dogs. The dogs are considered indoor, however they are let out for bathroom breaks in a fenced in area. This was the dogs first time receiving the product. She does treat year round with an unknown flea and tick product. There are 2 other cats in the home that are also being treated with FRONTLINE PLUS (Please see case 19US036591). No further information at this time. UPDATE 3 JUL 2019: Case updated to Inquiry due to treatment program not respected. UPDATE: On 23 Jul 2019, the animal owner reported the following: 06 Jul 2019: The second dose of FRONTLINE PLUS DOG 23-44 LBS one pipette per canine was applied topically between the shoulders. 07 Jul 2019: The owner reports seeing a large amount of fleas on both of the pets. They have not presented to the veterinary clinic. No additional treatments have been initiated. Their current condition is ongoing. No further medical information expected. UPDATE 24 JUL 2019: Case remains Inquiry due to treatment program not respected. UPDATE: 12 Sep 2019: As reported by the owner, on 07 Aug 2019 The third dose of FRONTLINE PLUS DOG 23-44 LBS one

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 309 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00316

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											pipette per canine was applied topically between the shoulders. 08 Aug 2019: The dogs still have an unknown amount of fleas. Their current condition is unknown. No further medical information expected.
01-Jul-2019	UAE; 19US038095; NY; U.S.A	Species: Feline Breed: Russian Blue Sex: F Sex qualifier: Neutered Age: 7.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	15-Mar-2019	15-Mar-2019	0 Day(s)	D-D	Suspected Adverse Event: On 28 Jun 2019, the owner reported the following event for Lily, 7 year old, spayed female, Russian Blue Feline. 15 Mar 2019: One vial of FRONTLINE PLUS CATS (R41105AW) was applied between the shoulder blades. After an unknown amount of time the cat experienced drooling and vomiting. 16 Mar 2019: The cat presented to the clinic. No treatment was provided. The cat recovered. The cat has received the product on prior unknown dates with no issue. No further medical information is expected. Product quality: On 28 Jun 2019, the pet owner reported the following issue with FRONTLINE PLUS CATS (R41105AW) 3 pack. The 3 vials in the box were for FRONTLINE PLUS DOG 45-88 LBS. The lot number on the vials and box matched. The order number on the invoice is 111-1564932-3446623. The product came from Amazon LLC. The owner purchased the product on 10 Mar 2019. The owner has not contacted Amazon about the matter. Product return and pictures of product and invoice are expected. No further information
01-Jul-2019	UAE; 19US038111; VA; U.S.A	Species: Canine Breed: Large crossbred (>20 Kg) Sex: M Sex qualifier: Neutered Age: 6.00 Year(s) Weight: 57 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: AFOXOLANER 68 MG CHEWABLE TABLETS; Route: Topical / Cutaneous Was the product used ok?: Yes	23-Jun-2019	21-Jun-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 1 Jul 2019, the pet owner reported the following event for Nacho a male neutered, 57 pound, 6 year old, Large Crossbreed. Unknown dates: The pet owner administered NEXGARD (lot number unknown, expiration unknown) (Product unsubstantiated) to the dog. 21 Jun 2019: The pet owner first noticed 5-15* fleas on the dog. 23 Jun 2019: The pet owner applied one dose of FRONTLINE PLUS DOG 45-88 LBS (lot number unknown) topically to skin between the shoulder blades of Nacho for the first time. 24 Jun 2019: The pet owner continued to see 5-15* fleas on the dog. Nacho was in good health at time of application. Nacho was not presented to veterinarian. The home environment has been treated by pet owner. The pet owner has seen fleas in the home. Nacho has no history of skin problems or any other issues with topical treatments. Nacho has not had flea problem before in the past. Nacho has not received any other topical treatments. Nacho has not been bathed. Nacho is indoors and outside for walks. The current status of Nacho is unknown. Nacho share home with 1 other cat that is treated with FRONTLINE PLUS CATS (S40606AW) with flea issues and case number 19US038128. No further medical information. UPDATE 5 Sept 2019: The no further information box was checked. No further medical information expected.
01-Jul-2019	UAE; 19US038112; -; U.S.A	Species: Feline Breed: Maine Coon Cat Sex: M Sex qualifier: Neutered Age: - Weight: 12.5 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products	23-Jun-2019	01-Jul-2019	8 Day(s)	D-D	Suspected Lack of Efficacy: On 1 Jul 2019, a pet owner reported the following event for a 12.5 pound, male neutered Maine Coon. Jan 2019*: The owner started using FRONTLINE PLUS CATS (lot unknown) topically at the base of the neck between the shoulder blades, the owner is applying every 28 days. 23 Jun 2019: The last dose was applied. 1 Jul 2019: The owner is still seeing live fleas on the cat. There is only 1 cat in the house. The owner is treating the carpet and the

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 310 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00317

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Route: Topical / Cutaneous Was the product used ok?: Yes					house. It is unknown if the cat goes outside. All further details are unknown. No further medical information expected.
01-Jul-2019	UAE; 19US038144; TX; U.S.A	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: M Sex qualifier: Neutered Age: 15.00 Month(s) Weight: 13 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	17-Jun-2019*	19-Jun-2019*	2 Day(s)	D-D	Suspected Adverse Event and Suspected Lack of Efficacy Claim : On 1 Jul 2019, the owner reported the following event for Jax, a 15 month old (born 1 Mar 2018), 13 pound, neutered male, Domestic Shorthair crossbreed. 17 Jun 2019*: Started on 1 vial of FRONTLINE PLUS CATS (S40717AW) topically between the shoulder blades by the owner. The cat had fleas prior to the first application. 19 Jun 2019*: The cat had hair loss and scabs at the application site. The owner was still seeing fleas. The cat was not seen by a veterinarian or given any treatment. The symptoms are ongoing. There was another cat in the home also treated with FRONTLINE (see case 19US038151). No further medical information expected.
01-Jul-2019	UAE; 19US038183; FL; U.S.A	Species: Feline Breed: Feline (unknown) Sex: F Sex qualifier: Unknown Age: 6.00 Month(s) Weight: 3.5 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	17-Feb-2019	18-Jun-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 1 Jul 2019, the pet owner reported the following event for Harley, a female intact, 3.5 pound, 6 month old feline, other signalment unknown. 1 Feb 2019*: The pet owner first noticed 15+ fleas on the cat. 17 Feb 2019-17 Jun 2019: The pet owner applied one dose of FRONTLINE PLUS CATS (S40606AW) topically between the shoulder blades to the body of Harley monthly. 18 Jun 2019: The pet owner still noticed 15+ fleas on the body of Harley Harley was in good health at time of application. Harley was not presented to veterinarian. The home environment has been treated by pet owner. The cat was bathed on the 16th of every month and weekly thereafter with Dawn dish soap. The pet owner has seen fleas in the home. Harley has no history of skin problems or any other issues with topical treatments. Harley has not had flea problem before in the past. Harley has not received any other medications or topical treatments. Harley is indoors only. The current status of Harley is unknown. No further medical information.
01-Jul-2019	UAE; 19US038191; NY; U.S.A	Species: Canine Breed: Pit Bull Sex: M Sex qualifier: Neutered Age: 9.00 Year(s) Weight: 60 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-Jun-2019	28-Jun-2019	27 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 01 Jul 2019, Animal owner reported the following event for Shortcut, a 9 year old, 60 pound, neutered male pitbull. 01 Jun 2018: Started monthly FRONTLINE PLUS DOG 45-88 LBS (Lot unknown) topically between the shoulder blades. The most recent purchase of a 3 pack was on 08 Jun 2019. 01 Jun 2019: A dose was applied 28 Jun 2019: The pet owner started seeing live fleas on the dog. The dog is mostly outdoors with access to 5 acres of woods. The dog does not come in the house but is allowed into the garage. The dog has not been bathed. There is one cat who also has the same living conditions (reported in case 19US038212). No further information expected.
01-Jul-2019	UAE; 19US038212; NY; U.S.A	Species: Feline Breed: Feline (unknown) Sex: M Sex qualifier:	2	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON	01-Jun-2019	28-Jun-2019	27 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 01 Jul 2019, Animal owner reported the following event for a 12 pound, neutered male unknown breed cat. 01 Jun 2018: Started monthly FRONTLINE PLUS CATS (Lot unknown) topically between the shoulder blades. The most recent

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 311 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

v1.2

ED_005739D_00014390-00318

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Neutered Age: - Weight: 12 lbs				Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes					purchase of a 3 pack was on 08 Jun 2019. 01 Jun 2019: A dose was applied 28 Jun 2019: The pet owner started seeing live fleas on the dog. The cat is mostly outdoors with access to 5 acres of woods. The cat does not come in the house but is allowed into the garage. The cat has not been bathed. There is one dog who also has the same living conditions (reported in case 19US038191). No further information expected.
01-Jul-2019	UAE; 19US038219; WI; U.S.A	Species: Canine Breed: Wheaton Terrier Sex: M Sex qualifier: Neutered Age: 5.00 Year(s) Weight: 49 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	15-Jun-2018*	24-Jun-2019	9 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 1 Jul 2019, the pet owner reported the following event for Aston, a male neutered, 49 pound, 5 year old, Wheaton Terrier. Unknown dates: The pet owner administers unknown anti-inflammatory medication to dog. 15 Jun 2018*-15 Jun 2019*: The pet owner applied one dose of FRONTLINE PLUS DOG 45-88 LBS (S61314AR) topically to skin between the shoulder blades of Aston monthly on year round basis. 24 Jun 2019: The pet owner first noticed 15+ fleas on the dog. The pet owner applied one dose of FRONTLINE PLUS DOG 45-88 LBS topically to skin between the shoulder blades of Aston monthly. Aston was in good health at time of application. Aston was not presented to veterinarian. The home environment has been treated by pet owner. The pet owner has seen fleas in the home. Aston has no history of skin problems or any other issues with topical treatments. Ashton is bathed every 3 days with Lift hyopallergnic shampoo. Aston has not had flea problem before in the past. Aston has not received any other topical treatments. Aston is indoors and outside for walks. The current status of Aston is unknown. No further medical information.
01-Jul-2019	UAE; 19US038247; IL; U.S.A	Species: Canine Breed: American Bully Sex: F Sex qualifier: - Age: 8.00 Month(s) Weight: 45 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	17-Jun-2019*	24-Jun-2019*	1 Week(s)	D-D	Suspected Adverse Event: On 1 Jul 2019, the owner reported the following event for Nyla, 8 months, 45 pounds*, Non-pregnant non lactating female, American Bully. 17 June 2019*: One vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown) was applied between the shoulder blades, by the pet owner. 24 June 2019*: The dog had a rash at the application site. The pet owner stated for treatment she has been keeping dog inside and washing the bedding. 1 Jul 2019: The rash on the dog has spread to the back of the pet. No further medical information is expected.
01-Jul-2019	UAE; 19US038259; NY; U.S.A	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: F Sex qualifier: Neutered Age: 9.00 Year(s) Weight: 9 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	30-Jun-2019	01-Jul-2019	1 Day(s)	D-D	Suspected Adverse Event: On 1 Jul 2019, the owner reported the following event for Maxi, 9 year old, 9 pound, spayed female, Domestic Shorhair Feline. 30 Jun 2019: One vial of FRONTLINE PLUS CATS (S40815AW) was applied between the shoulder blades. 1 Jul 2019: The next morning the owner notice a bald spot localized at the application site. The pet did not present to the clinic and no treatment was provided. Symptoms are still ongoing. The cat has received the product seasonally since (2010*). The cat experiencing the same symptoms on a prior unknown date. No further medical information is expected.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 312 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00319

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
01-Jul-2019	UAE; 19US038266; NJ; U.S.A	Species: Canine Breed: Retriever (Labrador, Yellow) Sex: F Sex qualifier: Neutered Age: 4.00 Year(s) Weight: 45 - 55 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	17-Jun-2019	17-Jun-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 1 Jul 2019, the pet owner reported the following event for Bella, a 4 year old, 45 to 55 pound*, female spayed, Retriever Pitbull mix. 17 Jun 2019: 1 vial of FRONTLINE PLUS DOG 45-88 LBS(S6211AL) in one area between the shoulder blades with half of the product getting onto the dogs fur and the other half on the skin. The owner has been combing 20-30 fleas off of the dog daily since the application. The owner treats seasonally, the first application of FRONTLINE to the dog was in May. The dog goes out for potty breaks and recreation in fenced in yard where urban wildlife is present. There are 4 cats in the home who are treated with FRONTLINE PLUS CATS and are not having an issue with fleas. The dog has not had a bath recently and has a history of flea allergy dermatitis. No further medical information is expected.
01-Jul-2019	UAE; 19US038271; MS; U.S.A	Species: Canine Breed: Chihuahua Sex: F Sex qualifier: Neutered Age: 3.00 Year(s) Weight: 13 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	27-Jun-2019	30-Jun-2019	3 Day(s)	D-D	Suspected Lack of Efficacy Claim: 01 Jul 2019: An owner reported the following event in Foxy; a 3 year old, 13 pounds, spayed, female, Chihuahua mix. 27 Apr 2019: The owner administered one tube of FRONTLINE PLUS DOGS 5-22 LBS (lot unknown, package unavailable) topically in an unknown manner. 27 May 2019: The owner administered one tube of FRONTLINE PLUS DOGS 5-22 LBS (lot unknown, package unavailable) topically in an unknown manner. 27 Jun 2019: The owner administered one tube of FRONTLINE PLUS DOGS 5-22 LBS (lot unknown, package unavailable) topically in an unknown manner. 30 Jun 2019: The owner saw 2 fleas on the dog. There are no other animals in the home. No further medical information expected.
01-Jul-2019	UAE; 19US038275; KY; U.S.A	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: 92 lbs	4	4	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	17-Jun-2019*	18-Jun-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 1 July 2019, the owner reported the following event for 4 dogs about 92 ponds (signalment unknown). *17 June 2019: One vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown) was topically applied to the skin between the shoulder blades to each dog. *Unknown date: The dogs started to pick up a large number of fleas on a daily basis. The dogs have been treated with FL monthly year round and haven't had any prior issues with fleas on prior application. The yard is treated for fleas and there are currently not any fleas in the home. No further information available.
01-Jul-2019	UAE; 19US038292; -; U.S.A	Species: Feline Breed: Domestic Mediumhair (Crossbred) Sex: F Sex qualifier: Neutered Age: - Weight: 9 lbs	2	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used	17-Jun-2019	17-Jun-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 1 Jul 2019, the pet owner reported the following event for Gidget, a 9 pound, female spayed Domestic mediumhair. 17 Jun 2019: 1 vial of FRONTLINE PLUS CATS (S40815AW) was applied to the cat in one area between the shoulder blades. The owner has been seeing 5-10 fleas on the cats daily since the application. The owner treats seasonally 8 months out of the year, First application Jun 2019. The cats in indoor only and not history of skin issues and has not had a bath recently. There is 1 dog in the home treated with FRONTLINE and not having an issue with fleas. There is one cat in the home treated with Advantage, and 1 cats

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 313 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00320

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						ok?: Yes					outdoors not treated. There is one other cat in the home treated with FRONTLINE having an issue with fleas, see case 19US40098. No further medical information.
01-Jul-2019	UAE; 19US038316; CA; U.S.A	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	3	3	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	24-Jun-2019	24-Jun-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 1 July 2019, the owner reported the following event for 3 cats (signalment unknown). 24 June 2019: One vial of FRONTLINE PLUS CATS (lot unknown) was topically applied to the skin between the shoulder blades. *Unknown date: The cats started to pick up fleas. The cats are treated monthly with FL and it is unknown by the reporter how long the fleas have been on the cats. The cats are indoor and outdoor and they have access to dirt, plants, and a stone area. The have been a few fleas seen in the home. No further information available.
01-Jul-2019	UAE; 19US038319; OH; U.S.A	Species: Feline Breed: Feline (various breeds) Sex: F Sex qualifier: - Age: 6.00 Month(s) Weight: 7 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	22-Jun-2019	22-Jun-2019	0 Day(s)	D-D	Suspected Adverse Reaction: On 24 Jun 2019, the pet owner reported the following event for Arabella, a female intact, non-pregnant, non- lactating, 7 pounds, 6 month old, Feline mixed/ various breeds. 22 Jun 2019: The pet owner applied one dose of FRONTLINE PLUS CATS (S40404AW) topically to skin between the shoulder blades of the cats for the first time. Arabella experienced diarrhea 3* hours post application. 23 Jun 2019: Arabella recovered from diarrhea. The cat was in good health at time of application. The cat was not presented to veterinarian. The home environment has not been treated by pet owner. The pet owner has not seen fleas in the home. The cat has no history of skin problems or any other issues with topical treatments. The cat has not had flea problem before in the past. The cat shares FRONTLINE PLUS CATS with one other cat that has case number 19US036755. The cat has not received any other medications or topical treatments. The cat has not been bathed. The cat is indoors and outside. The current status of the cat is unknown. No further medical information.
01-Jul-2019	UAE; 19US038324; IN; U.S.A	Species: Canine Breed: Retriever (Golden) Sex: F Sex qualifier: Neutered Age: 3.00 Year(s) Weight: 64 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: PO-Oral Was the product used ok?: Yes	19-Jun-2019	01-Jul-2019	12 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 01 Jul 2019 a clinic staff reported the following event in Lulu, a 3 year old, 64 pound, female spayed Golden Doodle. 19 Jun 2019: The canine was administered one vial of FRONTLINE PLUS DOG 45-88 LB (S61111) for the first time. No fleas at time of administration. 01 Jul 2019: The canine presented to the veterinarian for unspecified reasons. At time of exam fleas were seen. The veterinarian prescribed Bravecto. There are no housemates. No further information provided nor expected.
01-Jul-2019	UAE; 19US038383; NY; U.S.A	Species: Canine Breed: Yorkshire Terrier Sex: M Sex qualifier: Neutered Age: 10.00 Year(s) Weight: 8 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products	30-May-2009*	01-May-2019*	N/A	D-C	Suspected Adverse Event and Suspected Lack of Efficacy : On 1 July 2019, the pet owner reported the following event for Mylo, a 8 pound, 10 year old, male neutered, Yorkshire Terrier Poodle mix. 30 May 2019: 1 vial of FRONTLINE PLUS DOG 5-22 LBS (S61006AL) was applied to the dog in one area between the shoulder blades. 4 Jun 2019*: The dog began having uncontrollable twitching, loose stool, trouble breathing. He went lame and was unable to walk.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 314 of 867

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

v1.2

ED_005739D_00014390-00321

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Route: Topical / Cutaneous Was the product used ok?: Yes					6 Jun 2019*: The symptoms resolved. The dog is positive for lyme disease and has received unknown treatments. The dog was in poor condition to prior to the application of FRONTLINE due to the lyme disease. The owner has been treating with FRONTLINE monthly since 2009*. No further medical information is expected.
01-Jul-2019	UAE; 19US038386; FL; U.S.A	Species: Canine Breed: Maltese Sex: F Sex qualifier: Neutered Age: 12.00 Year(s) Weight: 8.1 lbs	1	1	1	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: IVERMECTIN/P YRANTEL PAMOATE CHEWABLE 68MCG/163MG; Vetmedin pimobendan chewable 1.25 mg NP; Benadryl; Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	27-May-2019	14-Jun-2019	18 Day(s)	D-A	Suspected Adverse Event: On 1 Jul 2019 the pet owner reported the following event for Lola Bella, a 12 year old (born 20 Jun 2006), 8.1 pound, spayed female Maltese. 1 Oct 2006*: Started on HEARTGARD PLUS (68 MCG/57 MG) (lot and expiration unknown) and FRONTLINE PLUS DOG 5-22 LBS (lot and expiration unknown) once monthly. 1 Jul 2007*: The canine was diagnosed with an unknown graded heart murmur. 3 Apr 2019: Started on VETMEDIN (PIMOBENDAN) 1.25 mg Chewable Tablet (lot and expiration unknown), 0.17 mg/kg, twice daily. 14 Jun 2019: The canine began exhibiting lethargy. 16 Jun 2019: Started on Benadryl once daily. 27 Jun 2019: The patient presented to the clinic and was hospitalized with suspected pneumonia. Upon performing a tracheal wash, the lungs began to bleed and the canine was diagnosed with an unknown form of cancer. A performed CBC indicated a low platelet count and the patient was humanely euthanized. No further medical information is expected.
01-Jul-2019	UAE; 19US038390; CA; U.S.A	Species: Feline Breed: Feline (unknown) Sex: M Sex qualifier: Neutered Age: 12.00 Week(s) Weight: 10 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: Unknown Rabies; Unknown Booster Vaccine; Route: Topical / Cutaneous Was the product used ok?: Yes	17-Jun-2019	17-Jun-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 1 Jul 2019, the pet owner reported the following event for Stanley, a 12 week old, 10 pound, neutered male, of unknown breed. 17 May 2019: The patient began receiving FRONTLINE PLUS CATS(S40606AW). While it is unknown if fleas were present prior to the dosing, The owner states she was seeing fleas shortly after the dosing of FRONTLINE on this day. 17 Jun 2019: The pet continued FRONTLINE with another dose. The owner was still seeing fleas on this day. The FRONTLINE was applied correctly, the animal is an indoors cat, the animal does not get bathes, and no other medications were given along with the FRONTLINE. The owner states there are no fleas on her person or in the household. The owner has not sought additional treatments for the animal or the household. The owner did state that the cat got an unknown rabies vaccine on 28 Jun 2019 and an unknown booster vaccine on 24 Jun 2019*. The patient's current condition is ongoing. There a total of 2 canines and 1 feline in the household, the 2 canines in the household are on preventatives and do not have fleas at this time. No further medical information expected
01-Jul-2019	UAE; 19US038392; NC; U.S.A	Species: Canine Breed: Canine various breeds Sex: X Sex qualifier: Mixed	3	3	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products	01-Jun-2019	01-Jul-2019	30 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 01 Jul 2019, animal owner reported the following event for 3 dogs who weigh between 45-80 pounds. 01 Jan 2019: Started monthly FRONTLINE PLUS DOG 45-88 LBS (Lot unknown) topically between the shoulder blades with the most recent purchase of 6 doses in May 2019.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 315 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

v1.2

ED_005739D_00014390-00322

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: - Weight: 45 - 80 lbs				used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes					01 Jun 2019: A dose was applied. 15 Jun 2019: The dogs were bathed with dawn dish soap. 01 Jul 2019: The pet owner saw live fleas on all 3 dogs. The pet owner applied a dose. The dogs are indoor/ outdoor dogs on a farm and have access to pasture. The environment has not been treated. No further information expected.
01-Jul-2019	UAE; 19US038394; GA; U.S.A	Species: Feline Breed: Manx Sex: M Sex qualifier: Neutered Age: 13.00 Year(s) Weight: 8 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	24-Jun-2019	25-Jun-2019	1 Day(s)	D-D	Suspected Adverse Event: On 1 Jul 2019, a pet owner reported the following event for Joey, a 13 year old, 8* pound, neutered male Manx mix. 2007*: The cat began receiving monthly applications of FRONTLINE PLUS CATS (Lot and Expiration Unknown) topically between the shoulder blades in one spot, seasonally, as needed without any issues. 24 Jun 2019: The cat received 1 application of FRONTLINE PLUS CATS (R40515AW). 25 Jun 2019: The cat vomited several times that day and then did not vomit again. 26 Jun 2019: The pet owner noticed that the cat had hair loss at the application site and his skin was red. The pet owner applied neosporin to the skin for 2-3 days. 1 Jul 2019: The cat has not vomited anymore and the skin is no longer red but the hair loss at application site is still present. The cat did not present to the clinic. No further medical information expected.
01-Jul-2019	UAE; 19US038403; MD; U.S.A	Species: Canine Breed: Poodle (Miniature) Sex: M Sex qualifier: Neutered Age: 6.00 Year(s) Weight: 14.0 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	05-Jun-2019	21-Jun-2019	16 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 01 Jul 2019, the animal owner reported the following event for Fergus, a 6 year old (born 21 Jun 2013), 14.0 pound, neutered male Miniature Poodle Shih Tzu Mix. Sep 2018* through 05 Jun 2019: He received FRONTLINE PLUS DOG 5-22 LBS (S61006AL) one dose applied topically between the shoulders monthly year round. 21 Jun 2019: He began experiencing pruritus and a hot spot near his tail. He presented to the veterinary clinic. No diagnostics were performed. Treatments were initiated with prednisone and Clavamox. 30 Jun 2019: He was bathed in a Hartz brand shampoo. 01 Jul 2019: The owner noted a small amount of fleas on Fergus. He did not present back to the veterinary clinic. No additional treatments were initiated. His current condition is ongoing. The yard environment has trees and shrubbery that creates pockets of shaded areas. There is one canine on the same sized FRONTLINE PLUS (see case 19US038417). There are two canines which have received a different sized FRONTLINE PLUS that do not have signs of fleas. There are two felines which received Advantage that do not have signs of fleas. He has a pertinent medical history of hot spots and Lyme disease. He has a history of drug reactions to an unknown manufacturer's brand DAP. No further medical information expected.
01-Jul-2019	UAE; 19US038404; WA; U.S.A	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: M Sex qualifier: Neutered	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: FIPRONIL	01-Aug-2018*	01-Jul-2019	9 Month(s)	D-D	Suspected Lack of Efficacy Claim: On 1 Jul 2019, the pet owner reported the following event for Burrito, a 5 year old 15 pound male neutered Domestic Shorthair. 1 May 2019, 1 Jun 2019, and 1 Jul 2019: The pet owner applied a dose of FRONTLINE GOLD FOR CATS (lot unknown) down to the skin at the neck. 1 Jul 2019: The cat has had a moderate amount of fleas since the

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 316 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00323

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: 5.00 Year(s) Weight: 15 lbs				9.8% / S-METHOPREN E 11.8% / PYRIPROXYFE N 0.25% TOPICAL SOLUTION; unknown flea collar; Route: unknown Was the product used ok?: Unknown to Company					he was adopted about a year ago. The pet owner was using FRONTLINE PLUS FOR CATS (lot unknown) for several months before switching to FRONTLINE GOLD. There are fleas in the home jumping on the pet owner. The cat does go outside and there are a lot of trees, bushes, and wildlife in the area. The cat does not have dry skin and is bathed every few months. The pet owners have treated the house and used an unknown flea collar on unknown dates. No further medical information expected.
01-Jul-2019	UAE; 19US038417; MD; U.S.A	Species: Canine Breed: Terrier Breeds (500 Series) Sex: F Sex qualifier: Neutered Age: 5.00 Year(s) Weight: 20.00 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	05-Sep-2018*	01-Jul-2019	26 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 01 Jul 2019, the animal owner reported the following event for Penny, a 5 year old (born 24 Feb 2014), 20.0 pound, spayed female Terrier Long-Haired Dachshund Mix. Sep 2018* through 05 Jun 2019: She received FRONTLINE PLUS DOG 5-22 LBS (S61006AL) one dose applied topically between the shoulders monthly year round. 30 Jun 2019: She was bathed in a Hartz brand shampoo. 01 Jul 2019: The owner noted a small amount of fleas on Penny. She did not present back to the veterinary clinic. No treatments were initiated. Her current condition is ongoing. The yard environment has trees and shrubbery that creates pockets of shaded areas. There is one canine on the same sized FRONTLINE PLUS (see case 19US038403). There are two canines which have received a different sized FRONTLINE PLUS that do not have signs of fleas. There are two felines which received Advantage that do not have signs of fleas. No further medical information expected.
01-Jul-2019	UAE; 19US038433; CA; U.S.A	Species: Canine Breed: Pinscher (Miniature) Sex: F Sex qualifier: Neutered Age: 2.00 Year(s) Weight: 13 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	05-Jun-2019	26-Jun-2019	3 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 1 July 2019, the owner reported the following event for Freda, a 2 year old, 13 pound, spayed female miniature Pinscher/Dachshund. 5 June 2019: One vial of FRONTLINE PLUS DOG 5-22 LBS (S60810AX) was topically applied to the skin between the shoulder blades for the first time. 26 June 2019: The groomer found a small number of fleas on the dog. The dog is indoor and outdoor and she is exposed to grass on a daily basis. There are no fleas in the home. The dog is bathed once a month with oatmeal shampoo and she doesn't have any skin issues. There is one other FL treated dog in the home who also is having an issue with fleas. See case 19US038435. There are 2 cats in the home and it is unknown if they are on flea control. No further information available.
01-Jul-2019	UAE; 19US038435; CA; U.S.A	Species: Canine Breed: Terrier Breeds (500 Series) Sex: M Sex qualifier: - Age: 1.50 Year(s) Weight: 12 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products	05-Jun-2019	26-Jun-2019	3 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 1 July 2019, the owner reported the following event for Teddy, a 1.5 year old, 12 pound, intact male Terrier. 5 June 2019: One vial of FRONTLINE PLUS DOG 5-22 LBS (S60810AX) was topically applied to the skin between the shoulder blades for the first time. 26 June 2019: The groomer found a small number of fleas on the dog.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 317 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00324

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Route: Topical / Cutaneous Was the product used ok?: Yes					The dog is indoor and outdoor and he is exposed to grass on a daily basis. There are no fleas in the home. The dog is bathed once a month with oatmeal shampoo and he doesn't have any skin issues. There is one other FL treated dog in the home who also is having an issue with fleas. See case 19US038433. There are 2 cats in the home and it is unknown if they are on flea control. No further information available.
01-Jul-2019	UAE; 19US038493; IL; U.S.A	Species: Canine Breed: Shih Tzu Sex: M Sex qualifier: Neutered Age: 9.00 Year(s) Weight: 10 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	17-Jun-2019*	17-Jun-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 1 July 2019, the owner reported the following event for Dexter, a 9 year old, 10 pound, neutered male Shih Tzu. 17 June 2019: The owner noticed fleas on the dog and applied one vial of FRONTLINE PLUS DOG 5-22 LBS (S63009AL) topically to the skin between the shoulder blades. The dog continued to pick up a small number of fleas. The dog is exposed to grass daily for potty breaks and walks daily. The owner has found a few dead fleas in the home, but hasn't experienced fleas bites in the home. The dog is treated as needed and has been for years. There is one cat in the home who also is having an issue with fleas see case 19US038861. No further information available.
01-Jul-2019	UAE; 19US038497; PA; U.S.A	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: M Sex qualifier: Neutered Age: 1.00 Year(s) Weight: 6 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	12-Jun-2019	28-Jun-2019	16 Day(s)	D-D	Suspected Lack of Efficacy Claim: 01 Jul 2019: An owner reported the following event in Buddy; a 1 year old, 6 pounds*, neutered, male, Domestic Shorthair, outdoor cat. 12 May 2019: The owner administered one tube of FRONTLINE PLUS CATS (S41003AW) between the shoulder blades topically. 12 Jun 2019: The owner administered one tube topically between the shoulders. 28 Jun 2019: The owner saw 1-3 ticks and removed them. The owner is unsure if they were alive or dead but said they did not have blood in them when smashed. The cat fully recovered. There are no other animals in the home.
01-Jul-2019	UAE; 19US038513; CA; U.S.A	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: M Sex qualifier: Neutered Age: 14.00 Year(s) Weight: 10.7 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: EPRINOMECTIN 0.4% / PRAZIQUANTEL 8.3% SOLUTION; IMRAB 3 TF - 1905.26; FeloVac FVRCP; FelOVac Felv; Route: Topical / Cutaneous Was the product used ok?: Unknown	24-Jun-2019	27-Jun-2019	3 Day(s)	D-D	Suspected Adverse Event: On 1 Jul 2019, the clinic staff reported the following event for Zorro, a 14 year old (2005*) 10.7 pound male neutered Domestic Shorthair. 24 Jun 2019: The pet owner applied a dose of FRONTLINE (unsubstantiated) (lot unknown) at an unknown location. 25 Jun 2019: The veterinarian applied a dose of CENTRAGARD 5.6-16.5 LBS (CUS001AAA, Jan 2020) to the base of the neck and vaccinated with IMRAB 3 TF (18397, 16 Aug 2020) 1ml SC right hind, FeloVac FVRCP unknown location, and FelOVac Felv left shoulder. 27 Jun 2019: The cat had redness and hair loss at the base of the neck. The cat's status was the same at the time of the phone call. The cat has not had the CENTRAGARD prior, it is unknown if the cat has received the FRONTLINE or IMRAB prior. No further medical information expected.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 318 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00325

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
01-Jul-2019	UAE; 19US038521; OR; U.S.A	Species: Feline Breed: Feline various breeds Sex: M Sex qualifier: Neutered Age: - Weight: 8 lbs	2	2	0	to Company Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: Flea shampoo; Route: Topical / Cutaneous Was the product used ok?: Yes	28-Apr-2019	29-Jun-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 1 Jul 2019 the pet owner reported the following event for the following 2 felines, Thomas an 8 pound male neutered feline (unknown) And Jasper an 8 pound male neutered Siamese. All other signalments are unknown. *Apr 2019: The owner applied 1 vial of FRONTLINE PLUS CATS (UNKNOWN) to the skin between the shoulder blades for the first time and repeated it monthly thereafter. The owner was seeing fleas for an unknown amount of time. *May 2019: The owner applied another dose. 29 Jun 2019: The owner began seeing a large amount of fleas on the cats. The owner flea bombed the house and bathed both cats in a flea shampoo. Once dry the owner applied another dose less than 30 days after the last dose. There are no other pets in the home. The owner is noticing flea activity inside of the home. No further medical information is available. UPDATE: 10 JUL 2019: The following information was recieved via email from the owner. 28 Apr 2019: The first dose was administered. 28 May 2019: The second dose was administered. No further medical information expected.
01-Jul-2019	UAE; 19US038526; -; U.S.A	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	26-Jun-2019*	01-Jul-2019*	5 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 1 Jul 2019, the pet owner reported the following event for a cat of unknown signalment. 26 Jun 2019*: The patient began receiving FRONTLINE PLUS CATS(lot unknown). 1 Jul 2019*: The owner noticed fleas. It is unknown if the owner saw fleas prior to the dosing. The cat does not go outside, there are no other animals in the household, and the owner has not seen fleas in the house. This is potentially the cat's first dose of FRONTLINE, but the owner is unsure. The patient's current condition is ongoing. The owner refused further inquiry. No further medical information expected.
01-Jul-2019	UAE; 19US038561; PA; U.S.A	Species: Canine Breed: Small crossbred (<10 Kg) Sex: U Sex qualifier: Unknown Age: 1.00 Year(s) Weight: 7 - 10 lbs	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	17-Jun-2019*	18-Jun-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 1 Jul 2019 the pet owner reported the following event for 2 unknown 1-6 year old, 7-10 pound, Small crossbred (<10 Kg) dogs. All other signalments are unknown. *17 Jun 2019: The owner applied 1 vial of FRONTLINE PLUS DOG 5-22 LBS (UNKNOWN) to the skin between the shoulder blades for the first time. It is unknown if the owner was seeing fleas prior to the application. *18 Jun 2019: The owner continued seeing a medium amount of fleas on the dog. There are no other pets in the home. The owner is not noticing any indoor flea activity. The outdoor environment of the dogs is unknown. It is unknown if the dogs get bathed or have skin issues. No further medical information is expected.
01-Jul-2019	UAE; 19US038563; MN; U.S.A	Species: Canine Breed: Medium crossbred (10 - 20 Kg) Sex: F	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON	17-Jun-2019	18-Jun-2019*	13 Day(s)	D-C	Suspected Lack of Efficacy Claim and Suspected Adverse Event : On 1 July 2019, the owner reported the following event for Hope, a 2 year old, 25 pound, spayed female mixed breed dog. 17 June 2019: One vial of FRONTLINE PLUS DOG 23-44 LBS (FL) (S61009AL) was topically applied to the skin between the

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 319 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00326

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: Neutered Age: 2.00 Year(s) Weight: 25 lbs				Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes					shoulder blades for the first time. 30 June 2019: Hope front leg was in discomfort and she appeared to be in pain. Hope will be seen by the vet tomorrow. She isn't on any other medications, doesn't have any medical conditions, and is in good health. There is one other dog in the home treated with a different weight category of FL. No further information available. UPDATE 11 Jul 2019: Per the pet owner, the dog tested Lyme positive on an unknown date and was treated with an unknown antibiotic. No further medical information expected. UPDATE 11 Jul 2019: Per pet owner, the dog presented to the clinic on 2 Jul 2019 and tested Lyme positive. Owner stated today that she noted 1 to 2 ticks on the dog every day after applied FRONTLINE, which where attached and still alive. It is unknown if she was seeing ticks prior to application. There is one other dog in the home who also received FRONTLINE on the same date and the two dogs live inside and outside, with access to five acres of land. No further medical information expected.
01-Jul-2019	UAE; 19US038568; CA; U.S.A	Species: Feline Breed: Feline (unknown) Sex: F Sex qualifier: - Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	29-Jun-2019	30-Jun-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 1 Jul 2019 the pet owner reported the following event for an unknown female feline. All other signalments are unknown. 29 Jun 2019: The owner applied 1 vial of FRONTLINE PLUS CATS (S40503AX) to the skin between the shoulder blades. It is unknown if this was the first application. It is unknown if the owner was noticing flea activity prior to application. 30 Jun 2019: The owner began seeing fleas on the cat. There are no other pets in the home. The cat is an outdoor only cat that frequently hunts. It is unknown if the cat receives baths or has any skin conditions. No further medical information expected. Product quality: On 1 Jul 2019 the pet owner reported the following issue with an 8 pack of FRONTLINE PLUS CATS (S40503AX). The owner took the blister packs out of the package and noticed the dotted cut here line went over the bottom of the vial and would cause damage to the vial inside. The owner proceeded to but along the top of the blister package where the tip of the vial is located. When the owner attempted to peel the foil down the owner couldn't get the foil separated. The owner used scissors on the foil and accidentally punctured the vial. The liquid poured into the blister packaging. The owner then moved on to a second vial but this time slowly cut the blister packaging along the edge of the vial and did not damage the second vial. The owner reported the blister packaging as indestructible and poorly designed. The remaining 6 vials are undamaged and sealed in the original blister packaging. The damaged vial is not expected to be returned as the owner disposed of the vial. No further information is expected.
02-Jul-2019	UAE; 19US038572; MI; U.S.A	Species: Canine Breed: Yorkshire Terrier Sex: M Sex qualifier: Neutered Age: 8.00 Year(s) Weight: 9 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the	01-Jul-2019	01-Jul-2019	0 Day(s)	D-D	Suspected Adverse Event: On 2 Jul 2019, a pet owner reported the following event for Max, an 8 year old, 9 pound, male neutered Yorkshire Terrier. 2015: The dog started using FRONTLINE PLUS DOG S (product unsubstantiated)(lot unknown) for up to 10 kg, foreign label product. Unknown Dates: The owner reported the dog got sick, no further details in regards to those situations. 1 Jul 2019: The most recent dose was applied 1 dose topically between the shoulders in the morning. In the evening the dog began eating grass and vomited. 2 Jul 2019: The dog was walking with a tucked tail an the owners

N/A signifies the information for this field is either not available or not applicable

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

Report printed on 25-Oct-2019 at 8:39:59PM

*indicates Approximate date or weight

Page 320 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00327

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						product used ok?: No (Others)					were instructed to bathe the dog to remove the product. No further medical information expected.
02-Jul-2019	UAE; 19US038579; GA; U.S.A	Species: Canine Breed: Maltese Sex: F Sex qualifier: Neutered Age: 3.00 Year(s) Weight: 18 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: unknown flea shampoo; Dawn dish detergent; Route: Topical / Cutaneous Was the product used ok?: Yes	22-Apr-2019*	02-Jul-2019	10 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 2 Jul 2019, the pet owner reported the following event for Maggie, a 3 year old (22 Mar 2016), 18 pound, spayed female Maltese/West Highland White Terrier mix.. Unknown date, 1 Jan 2019*: The dog began receiving FRONTLINE PLUS DOG 5-22 LBS (S61902AL) monthly with 3 vials purchased on an unknown date from PetSmart. The product is applied directly on the skin between the shoulder blades. Apr 2019* through Jun 2019*: Monthly product application on unknown dates. 22 Jun 2019: The dog was scratching, and fleas were noticed on the dog after returning from the groomer. The pet owner applied the most recent dose. 24 Jun 2019*: The dog was bathed with an unknown flea shampoo and Dawn dish detergent. 2 Jul 2019: The owner is still noticing fleas. The dog goes on leash walks, and is allowed out in the yard, where there is a large oak tree. The owner did mention that fleas are noticed after the dog return in from outside. The dog has not presented to the veterinary clinic. The dog's current condition is ongoing. There a total of 1 canine and no other animals in the household. No further medical information expected.
01-Jul-2019	UAE; 19US038626; -, U.S.A	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: F Sex qualifier: Neutered Age: - Weight: 11 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	17-Jun-2019	17-Jun-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 1 Jul 2019, the pet owner reported the following event for May, a 11 pound, female spayed Domestic shorthair. 17 Jun 2019: 1 vial of FRONTLINE PLUS CATS (S40815AW) was applied to the cat in one area between the shoulder blades. The owner has been seeing 5-10 fleas on the cats daily since the application. The owner treats seasonally 8 months out of the year, First application Jun 2019. The cats in indoor only and not history of skin issues and has not had a bath recently. There is 1 dog in the home treated with FRONTLINE and not having an issue with fleas. There is one cat in the home treated with Advantage, and 1 cats outdoors not treated. There is one other cat in the home treated with FRONTLINE having an issue with fleas, see case 19US038292. No further medical information.
02-Jul-2019	UAE; 19US038633; WI; U.S.A	Species: Canine Breed: Retriever (Labrador, Black) Sex: M Sex qualifier: Neutered Age: 3.00 Year(s) Weight: 97 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-Jun-2019	11-Jun-2019*	10 Day(s)	D-C	Suspected Lack of Efficacy Claim: On 2 Jul 2019, a pet owner reported the following event for Bill, a 3 year old (born 1 Apr 2016), 97 pound, neutered male Black Labrador Retriever. 2015*: The dog began receiving monthly FRONTLINE PLUS DOG 89-132 LBS (Lot and Expiration Unknown) topically between the shoulder blades year round. 1 Jun 2019: The dog received 1 application of FRONTLINE. 11 Jun 2019*: The owner noticed that the dog's appetite started to decrease. 18 Jun 2019*: The dog presented to the clinic and tested Lyme antigen positive on a Snap 4 Dx test and was treated with doxycycline. The pet owner did not notice any ticks on the dog. No further medical information expected.
02-Jul-2019	UAE; 19US038648;	Species: Canine Breed: Pinscher	1	1	0	Product used: FIPRONIL	01-Jul-2019*	01-Jul-2019*	0 Day(s)	D-D	Suspected Adverse Event: On 2 Jul 2019, a pet owner reported the following event for a 12 pound Min Pinscher of further unknown

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 321 of 867

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

v1.2

ED_005739D_00014390-00328

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	-; U.S.A	(Miniature) Sex: U Sex qualifier: Unknown Age: - Weight: 12 lbs				10%/S METHOPRENE 9% SPOT ON Other products used: unknown shampoo; Route: Topical / Cutaneous Was the product used ok?: No (Contraindication per label)					signalment. 1 Jul 2019*: The owner applied FRONTLINE PLUS DOG 5-22LBS (lot unknown) topically by the shoulders. The owner said the dog cried out when a flea bit her. The owner bathed her in an unknown shampoo. The owner applied 2 drops of the FRONTLINE PLUS and the dog woke up 2 hours later gagging and trying to regurgitate. The owner bathed the dog again. The owner applied 2 more drops of FRONTLINE PLUS and the dog woke up 2 hours later and attempted to gag. 2 Jul 2019: The owner bathed the dog again. The owner took the dog to the RDVM and was told there was nothing that could be done. No further medical information expected.
02-Jul-2019	UAE; 19US038651; -; U.S.A	Species: Canine Breed: Canine (unknown) Sex: F Sex qualifier: Unknown Age: - Weight: 15 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	19-Jun-2019	02-Jul-2019	13 Day(s)	D-D	Suspected Lack of Efficacy Claim: 02 Jul 2019: An owner reported the following event in an unknown canine; 15 pounds, female, unknown repro status, unknown breed, indoor dog. 19 Jun 2019: The owner administered one tube of FRONTLINE PLUS DOGS 5-22 LBS (lot unknown, package unavailable) topically in an unknown manner for the first time. There were no fleas seen at the time of application. 02 Jul 2019: The owner is seeing an unknown amount of fleas. There is one other dog in the home, case 19US038638. No further medical information expected.
02-Jul-2019	UAE; 19US038668; WA; U.S.A	Species: Canine Breed: Retriever (Golden) Sex: F Sex qualifier: Neutered Age: 12.00 Year(s) Weight: Unknown	2	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	21-Jun-2019	28-Jun-2019	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 2 Jul 2019 the pet owner reported the following event for a 12 year old, female Golden Retriever of unknown further signalment. 21 Jun 2019: The pet owner applied FRONTLINE PLUS DOG 45-88 LBS (lot number unknown), 1 vial topically, in between the shoulder blades for the first time. Fleas were not seen at this time. 28 Jun 2019*: The pet owner bathed the canine and discovered 6 fleas. 2 Jul 2019: The canine was bathed with an unknown pet shampoo. Currently, the pet owner is still seeing fleas and is unsure if the canine weighs within the limits of the product. The canine spends equal times indoors and outdoors with access to a fenced in lawn. There is one pug in the home that is on FRONTLINE that is scratching, but is showing no signs of fleas (see case number 19US038705). There is also one 12 week old feline that is on an unknown brand of flea collar that is showing no signs of fleas. No further medical information is expected.
02-Jul-2019	UAE; 19US038685; WI; U.S.A	Species: Canine Breed: Retriever (Labrador, Black) Sex: M Sex qualifier: Neutered Age: 3.00 Year(s) Weight: 97 lbs	1	1	1	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: RECOMBITEK LYME - 2126.R0; Vetprofen; Route: unknown	01-Jun-2019*	14-Jun-2019	13 Day(s)	D-A	Suspected Lack of Efficacy Claim: On 2 Jul 2019, the pet owner reported the following event for Bill, a 3 year old, 97 pound, neutered male black Labrador Retriever. 19 Mar 2018, 12 Apr 2018, 1 Mar 2019: The dog was vaccinated with 1 mL RECOMBITEK LYME SC. 14 Jun 2019: The dog presented to the clinic experiencing lethargy and inappetence. 27 Jun 2019: The dog presented to the clinic with persistent lethargy and inappetence. The dog tested Lyme antigen positive on an unknown test and was additionally diagnosed with nephritis. Treatment was started with doxycycline, Enalapril and Omega 3 supplements.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 322 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00329

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Was the product used ok?: Unknown to Company					<p>The dog remains under treatment at this time. The dog has no prior history of Lyme testing. No further medical information expected.</p> <p>UPDATE 15 Jul 2019: Dog is continuing to decline, bloodwork was performed with unknown results. No further information available at this time.</p> <p>UPDATE 01 Aug 2019: Received records. 01 Mar 2019 RECOMBITEK LYME (42231, expiration 22 Oct 2020).</p> <p>14 Jun 2019: Dog was treated with Vetprofen for 7 days for lethargy.</p> <p>27 June 2019: creatinine 2.9 (0.5-1.8), BUN 30 (7-27), phosphorus 7.1 (2.5-6.8), albumin 2.0 (2.3-4.0), globulin 4.7 (2.5-4.4), ALP<10 (23-212), platelets 26 (148-484).</p> <p>28 June 2019 UPC 12.6 (proteinuric).</p> <p>02 July 2019 Quantitative C6 257 (>30 positive)</p> <p>05 July 2019: SDMA 21 (0-14), creatinine 2.3, BUN 48, albumin 1.3, UPC 12.8</p> <p>20 July 2019: SDMA 27, creatinine 2.7, BUN 46, albumin 1.1, globulin 2.5, Red Blood cells 3.71 (5.39-8.7), platelets 49, UPC 12.9, USPG 1.021, 3+ hematuria and 4+ proteinuria.</p> <p>30 July 2019: dog continues to be treated with benazepril and doxycycline. No further medical information is expected.</p> <p>UPDATE 02 Aug 2019: Added owner address to contact screen.</p> <p>UPDATE 8 Aug 2019: Per owner phone call, dog was on FRONTLINE(Unsubstantiated)(lot unknown, reporter not queried). The dates of usage are unknown. No further information is expected.</p> <p>UPDATE 03 Sep 2019: Per owner, dog was euthanized due to</p>
02-Jul-2019	UAE; 19US038691; IL; U.S.A	Species: Canine Breed: Retriever Labrador Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	01-Jun-2019*	02-Jun-2019*	1 Day(s)	D-D	<p>Suspected Lack of Efficacy Claim: On 2 Jul 2019, the pet owner reported the following event for a Retriever Labrador. All other signalments unknown, owner could not complete report.</p> <p>1 Jun 2019*: 1 vial of FRONTLINE PLUS DOG (product unsubstantiated, lot unknown) was applied to the dog in an unknown area. The owner has been seeing an unknown number of fleas on the dog since the application.</p> <p>The owner treats seasonally. There are fleas in the home. The dog goes out for potty breaks and recreation. There is one other dog in the home treated with Trifexis.</p>
02-Jul-2019	UAE; 19US038701; OK; U.S.A	Species: Canine Breed: Canine (unknown) Sex: F Sex qualifier: Neutered Age: 2.00 Year(s) Weight: 40 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: unknown pet shampoo for skin allergies; Route: Topical / Cutaneous Was the product used	26-May-2019	27-May-2019*	N/A	D-D	<p>Suspected Lack of Efficacy Claim: On 2 July 2019, a pet owner reported the following event for Red, a 40 pound, spayed female, Canine Mixed Breed following application with FRONTLINE PLUS DOG 23-44 LBS (S61009AL). The pet owners had purchased a 3 pack of this product on an unknown date; this date is unknown because the owner no longer had the store receipt.</p> <p>26 May 2019: Red received the first application of FRONTLINE PLUS DOG 23-44 LBS since having this same product applied on an unknown date in the past. There were no fleas present on the dog at the time of application nor were there any known infestations in the pet owner's house or outside environment. In an unknown amount of time post-application (reporter did not know the exact or approximately time), the pet owner observed an unknown number of fleas on the pet.</p>

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 323 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00330

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						ok?: Yes					26 June 2019: Red received another application of FRONTLINE PLUS DOG 23-44 LBS 2 July 2019: The pet owner found 4 fleas on the pet on this day (mild infestation), but has seen flea on her since the first application. The pet has since developed itching with flea allergy dermatitis and the pet owner is currently using a shampoo labeled for pets that have skin allergies. The home environment has not been treated to date as the pet owners report that they have not seen any fleas in their house and they have not been bitten by any fleas. There are no other dogs in the household and this is the first time that this pet has had a problem with a flea infestation. The patient is considered healthy outside of this issue. No other information is available.
02-Jul-2019	UAE; 19US038705; WA; U.S.A	Species: Canine Breed: Pug Sex: U Sex qualifier: Unknown Age: 15.00 Year(s) Weight: Unknown	2	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	21-Jun-2019	22-Jun-2019*	1 Day(s)	D-D	Suspected Adverse Event: On 2 Jul 2019 the pet owner reported the following event for a 15 year old Pug of unknown further signalment. 21 Jun 2019: The pet owner applied FRONTLINE PLUS DOG 5-22 LBS (lot number unknown), 1 mL topically, in between the shoulder blades. 22 Jun 2019*: The canine began exhibiting generalized pruritus. Currently, the pet owner states she is seeing no signs of fleas, that the canine is still exhibiting pruritus and has not received treatment. There is one other canine in the home that is on FRONTLINE that is exhibiting fleas (see case number 19US038668) and one 12 week old kitten that is on an unknown brand of flea collar that is not showing any signs of fleas. No further medical information is expected.
02-Jul-2019	UAE; 19US038725; NM; U.S.A	Species: Canine Breed: Poodle (Standard) Sex: F Sex qualifier: Neutered Age: 12.00 Year(s) Weight: 60 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: Galliprant; Gabapentin; Estrogen; SenoBG4; Route: Topical / Cutaneous Was the product used ok?: Yes	01-Jul-2019	02-Jul-2019	N/A	D-D	Suspected Adverse Event: On 2 Jul 2019, the pet owner reported the following event for Meka, a 60 pound, 12 year old, female spayed Poodle (Standard). 1 Apr 2019: 1 vial of FRONTLINE PLUS DOG 45-88 LBS(S62202AX) was applied to the dog in one area between the shoulder blades. 8 Apr 2019*: The hair at the application site turned yellow. 22 Apr 2019*: The hair started to turn back white. 1 May 2019: 1 vial of FRONTLINE was applied. 8 May 2019*: The hair turned yellow. 22 May 2019*: The hair went back to white. 1 Jul 2019: 1 vial of FRONTLINE was applied. 2 Jul 2019: The hair turned yellow. The dog has had FRONTLINE applied monthly since 2007. The dog takes Galliprant 60 mg a day, Gabapentin, Estrogen, and Senobg4. No further medical information is expected.
02-Jul-2019	UAE; 19US038762; IL; U.S.A	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	29-Jun-2019*	29-Jun-2019*	0 Day(s)	D-D	Suspected Adverse Event :On 2 Jul 2019, the owner reported the following event for the unknown female feline, all other signalment unknown. 29 Jun 2019*: One vial of FRONTLINE PLUS CATS (R41105) was applied topically in one location in-between the shoulder blades by the pet owner. Unknown date: The cat experienced hair loss at the application site and lethargy. It is unknown if the pet was presented to the clinic for treatment. The pet has been on the product for years per the owner from an unknown start date. It is unknown if the pet has recovered. No further medical information expected.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 324 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00331

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
02-Jul-2019	UAE; 19US038795; CA; U.S.A	Species: Canine Breed: Retriever (Labrador, Chocolate) Sex: M Sex qualifier: - Age: 12.00 Year(s) Weight: 75 - 77 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-Jan-2007	29-Jun-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 2 Jul 2019, the owner reported the following event for an unknown Canine , a 75-77 pound, 12 year old, male intact, Chocolate Labrador Retriever. 28 Jun 2019: One vial of the FRONTLINE PLUS DOG 45-88 LBS (Unknown) was applied topically in between the shoulder blades by the owner. Unknown date: The owner noticed a large amount of fleas on the pet. The dog is indoor/outdoor. The dog has access to a fenced in yard and beach area. This is the first time the owner has noticed fleas on the pet. The owner has used FRONTLINE since 2007 on the pet. This is the only pet within the home. The owner did bathe the pet in an unknown frequency to try to remove the fleas. Owner declined additional information. No further medical information is expected.
02-Jul-2019	UAE; 19US038809; NY; U.S.A	Species: Canine Breed: Terrier Breeds (500 Series) Sex: U Sex qualifier: Unknown Age: 9.00 Year(s) Weight: 25 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-Jul-2019	02-Jul-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 2 Jul 2019, the owner reported the following event for Dusty, 9 year old, 25 pound, Terrier canine. 1 Jul 2019: One vial of FRONTLINE PLUS DOG 23-44 LBS (S62704AW) was applied between the shoulder blades. 2 Jul 2019: The owner found 3 ticks that were attached and alive on the dog. The ticks were removed. The dog has received the product since 2014 with no issue. The dog has access to a open yard. There are no other pets in the household. No further medical information is expected.
02-Jul-2019	UAE; 19US038832; -, U.S.A	Species: Canine Breed: Large crossbred (>20 Kg) Sex: F Sex qualifier: Neutered Age: 4.00 Year(s) Weight: 80 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	24-Jun-2019*	01-Jul-2019	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: 02 Jul 2019: An owner reported the following event in Annie; a 4 year old, 80 pound, spayed, female, Large crossbred, indoor-outdoor canine. 17 May 2019*: The owner bathed the dog in an unknown flea shampoo. It is unknown if fleas were seen. 24 May 2019*: The owner applied one tube of FRONTLINE PLUS DOGS 45-88 LBS (lot unknown, package unavailable) topically between shoulder blades for the first time. It is unknown if fleas were seen. 24 Jun 2019*: *: The owner applied one tube of FRONTLINE PLUS DOGS 45-88 LBS topically between shoulder blades. An unknown amount of fleas were seen. 01 Jul 2019: The owner saw 3 fleas. There are no other animals in the home. No further medical information expected.
02-Jul-2019	UAE; 19US038839; IN; U.S.A	Species: Canine Breed: Small crossbred (<10 Kg) Sex: M Sex qualifier: Neutered Age: 13.00 Year(s) Weight: 11 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	15-Jun-2019	25-Jun-2019	10 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 02 Jul 2019, animal owner reported the following event for Henry, a 13 year old, 11 pound, neutered male mixed breed dog. 15 Jun 2019: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS DOG 5-22 LBS (Lot unknown) topically between the shoulder blades for the first time. 25 Jun 2019: The pet owner saw 5 live fleas and 1 dead flea. There is one cat in the home but owner has not seen fleas. The environment has not been treated and the dog has not been bathed. The dog is mostly indoors. No further information expected.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 325 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00332

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
02-Jul-2019	UAE; 19US038851; MO; U.S.A	Species: Canine Breed: Small crossbred (<10 Kg) Sex: F Sex qualifier: Neutered Age: 10.00 Month(s) Weight: 6 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	19-Apr-2019	20-Jun-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 2 Jul 2019, the pet owner reported the following event for Cookie, a female neutered, 6 pound, 10 month old, Small crossbred . 19 Apr 2019-19 Jun 2019: The pet owner applied one dose of FRONTLINE PLUS DOG 5-22 LBS (lot number unknown) topically to skin between the shoulder blades of Cookie monthly. 1 Jun 2019*: The pet owner noticed fleas on the body of Cookie. Cookie was in good health at time of application. Cookie was not presented to veterinarian. The home environment has not been treated by pet owner. The pet owner has seen fleas in the home. Cookie has no history of skin problems or any other issues with topical treatments. Cookie has not had flea problem before in the past. Cookie has not received any other medications or topical treatments. Cookie has not been bathed. Cookie is indoors and outside for walks. The current status of Cookie is unknown. No further medical information.
02-Jul-2019	UAE; 19US038860; TX; U.S.A	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-Jan-2019*	15-Jun-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 2 Jul 2019, a pet owner reported the following event for 2 canines of unknown signalment. Unknown Date: The owner began using FRONTLINE PLUS DOG 89-132 LBS (LOT UNKNOWN) 1 dose topically between the shoulder blades. 15 Jun 2019: The owner applied 1 dose of FRONTLINE per dog, fleas were present at application. 26 Jun 2019*: The owner bathed the dogs using an all natural coconut shampoo. The owner noticed the fleas were back after bathing the dogs. The dogs do go outside. All further details are unknown as the owner had to discontinue reporting during call. No further medical information expected.
01-Jul-2019	UAE; 19US038861; IL; U.S.A	Species: Feline Breed: Domestic Mediumhair (Crossbred) Sex: F Sex qualifier: Neutered Age: 2.00 Year(s) Weight: 5 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	17-Jun-2019	17-Jun-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 1 July 2019, the owner reported the following event for Patches, a 2 year old, 5 pound, spayed female Domestic Mediumhair. 17 June 2019: The owner noticed fleas on the cat and applied one vial of FRONTLINE PLUS CATS (lot unknown) to the skin between the shoulder blades. The cat continued to pick up a large amount of fleas. The owner has found a few dead fleas in the home, but hasn't experienced fleas bites in the home. The cat is treated as needed and has been for years. There is one dog in the home who also is having an issue with fleas see case 19US038493. No further information available.
02-Jul-2019	UAE; 19US038874; NC; U.S.A	Species: Canine Breed: Chinese Crested Sex: M Sex qualifier: Neutered Age: 11.00 Year(s) Weight: 14 lbs	2	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	24-Apr-2019	25-Apr-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 02 Jul 2019, animal owner reported the following event for DOG, 11 year old, 14 pound, neutered male, chinese crested. 24 Apr 2019: Started monthly FRONTLINE PLUS DOG 0-22 LBS (Lot unknown) topically between the shoulder blades for the first time. 25 Apr 2019: The pet owner noticed 2-3 live fleas on the dog. Fleas were not seen prior to the use of the product. 24 May 2019: A dose was applied and the pet owner was still seeing fleas on the dog. 24 Jun 2019: A dose was applied and still seeing fleas. 02 Jul 2019: The pet owner is still seeing fleas. The fleas are alive and range in sizes. The dog likes to lay in the back yard but is mostly indoors. The environment has been treated

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 326 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00333

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											and the dog has not been bathed. There is one other dog in the home but the pet owner has not seen fleas on that dog. No further information expected.
02-Jul-2019	UAE; 19US038893; IL; U.S.A	Species: Canine Breed: Shih Tzu Sex: M Sex qualifier: Neutered Age: 4.00 Year(s) Weight: 17 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-Apr-2019	02-Jul-2019	3 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 02 Jul 2019 an animal owner reported the following event in Kai, a 4 year old, 17 pound, male neutered, Shih Tzu Bichon Frise mix. 01 Apr 2019: The canine was administered 1 vial of FRONTLINE PLUS DOGS 5-22 LB (lot, expiration unknown. Package unavailable). No fleas seen at time of administration. 01 May 2019 and 01 Jun 2019: The canine was administered FRONTLINE PLUS. No fleas seen at time of administration. 23 Jun 2019: The animal owner noted dry skin at the base of the canine's tail. No fleas seen. 28 Jun 2019: A pet sitter noted that the canine was chewing paws and saw fleas on the canine. 29 Jun 2019: The canine was administered 1 vial of FRONTLINE PLUS. 02 Jul 2019: Fleas were seen by animal owner. There is a cat in the household. It has only received 1 CapStar on 29 Jun 2019. No fleas have been seen on the feline. There are neighborhood dogs and the canine goes to dog parks. No further information provided nor expected.
02-Jul-2019	UAE; 19US038900; CA; U.S.A	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: M Sex qualifier: Neutered Age: 7.00 Year(s) Weight: 14.2 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	18-Jun-2019*	02-Jul-2019	2 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 2 Jul 2019, the pet owner reported the following event for Jefferson, a 7 year old 14.2 pound male neutered Domestic Shorthair. 18 May 2019* and 18 Jun 2019*: The pet owner applied a dose of FRONTLINE PLUS CATS (lot unknown) down to the skin at the neck because the cat had fleas. 2 Jul 2019: The pet owner found a few fleas on the cat. It is unknown if this is the first time ever the cat has received FRONTLINE PLUS. No further medical information expected.
01-Jul-2019	UAE; 19US038905; IL; U.S.A	Species: Feline Breed: Domestic Mediumhair (Crossbred) Sex: F Sex qualifier: Neutered Age: 2.00 Year(s) Weight: 5 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	17-Jun-2019	30-Jun-2019	13 Day(s)	D-D	Suspected Adverse Event: On 1 July 2019, the owner reported the following event for Patches, a 2 year old, 5 pound, spayed female Domestic Mediumhair. 17 June 2019: One vial of FRONTLINE PLUS CATS (lot unknown) to the skin between the shoulder blades. 30 June 2019: Patches developed a loss in appetite. The owner is monitoring her on condition. Patches has been on FL as needed for years without any past issues. There are no other cats in the home. No further information available.
02-Jul-2019	UAE; 19US038907; AZ; U.S.A	Species: Canine Breed: Shih Tzu Sex: F Sex qualifier: Neutered Age: 3.00 Year(s) Weight: 17 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other	15-Jun-2019	02-Jul-2019	17 Day(s)	D-D	Suspected Lack of Efficacy Claim: 02 Jul 2019: An owner reported the following event in Zoey; a 3 year old, 17 pound, spayed, female, Shih Tzu, indoor-outdoor. 15 Feb 2019: The owner started applying one tube FRONTLINE PLUS DOGS 5-22 LBS (F6192AL) topically between the shoulders monthly. 15 Jun 2019: The owner applied one tube topically between the

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 327 of 867

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

v1.2

ED_005739D_00014390-00334

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						products Route: Topical / Cutaneous Was the product used ok?: Yes					shoulders. There were no fleas or ticks seen at the time of application. 02 Jul 2019: The owner found and removed 5 live ticks. 1 was alive, 4 were crawling on the dog. The dog fully recovered. There is one other dog in the home, they just got today. No further medical information expected.
02-Jul-2019	UAE; 19US038913; CA; U.S.A	Species: Feline Breed: Calico Sex: F Sex qualifier: Neutered Age: 6.00 Year(s) Weight: 20.0 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-Jul-2019	02-Jul-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 02 Jul 2019, the animal owner reported the following event for Nova, a 6 year old*, 20.0 pound, spayed female Calico. 01 Jul 2019: She received FRONTLINE PLUS CATS (lot unknown) one dose applied topically between the shoulders. 02 Jul 2019: The owner is noticing a large amount of fleas on the pet. The owner did note that the feline had fleas prior to administration. The owner is noticing fleas off of the feline inside the household. She is an indoor only feline. She has not presented to the veterinary clinic. No treatments have been initiated. Her current condition is ongoing. There are no other pets in the household. No further medical information expected.
02-Jul-2019	UAE; 19US038929; RI; U.S.A	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: M Sex qualifier: Neutered Age: 7.00 Month(s) Weight: 9 lbs	2	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-Jul-2019	02-Jul-2019	1 Day(s)	D-D	Suspected Adverse Event: 02 Jul 2019: An owner reported the following event in Tat-tat; a 7 month old, 9 pounds, neutered, male, Domestic Shorthair, indoor-outdoor, cat. 01 Jul 2019: Owner applied one tube FRONTLINE PLUS CATS (lot unknown, package unavailable) topically at the base of the neck for the second month in a row. 02 Jul 2019: The cat exhibited alopecia at the base of his tail. No fleas were seen. There is one other cat in the home that did not experience this. No further information available.
02-Jul-2019	UAE; 19US038940; OH; U.S.A	Species: Canine Breed: Canine various breeds Sex: X Sex qualifier: Unknown Age: 1.00 Year(s) Weight: 60.0 - 65.0 lbs	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-Apr-2019*	02-Apr-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 02 Jul 2019, the animal owner reported the following event for two unknown canines, a 1 year old* and a 14 year old*, unknown breeds, one female and one male of unknown reproductive status, and weighing 60.0 to 65.0 pounds*. 01 Apr 2019*, 01 May 2019*, 01 Jun 2019*, 29 Jun 2019: They received FRONTLINE PLUS 45-88 LBS (S63106AX) one dose per each dog applied topically between the shoulders. 02 Apr 2019*: The owner has been noticing a large amount of fleas on both of the canines. The owner noted both canines had fleas prior to application. The owner is not seeing fleas off of the canines inside the household as the canines are not allowed indoors. The canines are bathed every one to two weeks in a pet approved shampoo. There are no other pets in the household. No further medical information expected.
02-Jul-2019	UAE; 19US038969; FL; U.S.A	Species: Feline Breed: Domestic Mediumhair (Crossbred) Sex: F Sex qualifier: Neutered Age: 15.00 Year(s)	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: Dawn;	20-Apr-2019	20-May-2019	30 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 2 July 2019, the owner reported the following event for CoCo, a 15 year old, 11 pound, spayed female Domestic Mediumhair. 20 April 2019: The cat had fleas before the application for an unknown length of time and one vial of FRONTLINE PLUS CATS (FL) (S40502AX) was applied to the skin between the shoulder blades for the first time. The cat continued to have fleas. 20 May 2019: The cat had fleas and FL was reapplied.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 328 of 867

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00335

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: 11 lbs				Route: Topical / Cutaneous Was the product used ok?: Yes					20 June 2019: The cat continued to have fleas. The cat is strictly indoors and is bath once a month with Dawn. The owner is finding a large number of fleas on the cat and is noticing fleas in the home which is being treated. There is a dog in the home also having an issue with fleas, see case 19US039072. No further information available.
03-Jul-2019	UAE; 19US039013; MI; U.S.A	Species: Feline Breed: Feline various breeds Sex: X Sex qualifier: Neutered Age: 1.50 Year(s) Weight: 12 - 18 lbs	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	21-Jun-2019*	03-Jul-2019	12 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 3 Jul 2019, the pet owner reported the following event for 2 cats, Boomer, a male neutered, 1.5 year old, 18 pound, other signalment unknown, Lizzy, a female spayed, 12 pounds, 8 years old, Feline mixed/ various breeds. 21 Jun 2019*: The pet owner applied one dose of FRONTLINE PLUS CATS (S41003AW) topically to skin between the shoulder blades of the cats for the first time. 3 Jul 2019: The pet owner first noticed unknown amount of fleas on the cats. The cats were seen by veterinarian but were not treated. The cats were in good health at time of application. The home environment has not been treated by pet owner. The cats have no history of skin problems or any other issues with topical treatments. The cats have had flea problem before in the past and it resolved. The cats have not received any other medications or topical treatments. The cats have not been bathed. Lizzy is indoors only and Boomer is indoors and outside. The current status of the cats are unknown. No further medical information.
03-Jul-2019	UAE; 19US039027; MI; U.S.A	Species: Canine Breed: Pit Bull Sex: F Sex qualifier: Unknown Age: 12.00 Month(s) Weight: 60 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: FIPRONIL 9.8% / S-METHOPRENE 8.8% / PYRIPROXYFEN 0.25% TOPICAL SOLUTION; Route: Topical / Cutaneous Was the product used ok?: Yes	01-Dec-2018*	01-Feb-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 3 Jul 2019, the pet owner reported the following event for Daisy, a 12 month old, 60 pound, intact female, Pit Bull. 1 Feb 2019: The owner noticed some fleas after applying FRONTLINE PLUS (lot and expiration unknown). 1 Mar 2019: The patient began receiving FRONTLINE GOLD DOG 45-88 LBS (PP23481) because the owner had heard it worked better and the dog still had some fleas. 1 Apr 2019: The patient got another dose of FRONTLINE GOLD DOG 45-88 LBS. The owner was still noticing fleas at this time. 1 May 2019: The patient got another dose of FRONTLINE GOLD DOG 45-88 LBS. The owner was still noticing fleas at this time. 1 Jun 2019: The patient got another dose of FRONTLINE GOLD DOG 45-88 LBS. The owner was still noticing fleas at this time. 1 Jul 2019: The patient got another dose of FRONTLINE GOLD DOG 45-88 LBS. The owner was still noticing fleas at this time and is still seeing them as of 3 Jul 2019. The owner stated she is applying the FRONTLINE correctly, is not bathing the animal, and is not giving anything else at the time of giving FRONTLINE. The owner states the patient does go outside, and the yard is open access with the only wild animal seen are the squirrels in the owner's yard. There are also fleas in the house and they are on the owner biting them as well. The owner stated she is spraying a growth inhibitor around the house, and has not sought further treatments for her animal other than FRONTLINE. The patient's current condition is ongoing. There is a total of 1 canine and 3 felines in the household. These cats each have their own case as they were also on FRONTLINE and had fleas see cases 19US039712, 19US039722, and 19US039724. No further medical information expected.
03-Jul-2019	UAE; 19US039065;	Species: Canine Breed: Canine	1	1	0	Product used: FIPRONIL	05-May-2019	19-May-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 3 Jul 2019, the owner reported the following event for a 19.5 pound canine (all other

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 329 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00336

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	CA; U.S.A	(unknown) Sex: U Sex qualifier: Unknown Age: - Weight: 19.5 lbs				10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes					signalments unknown). 5 May 2019: A 6 pack of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) was purchased. One vial was applied between the shoulder blades for the very first time. 19 May 2019: The owner found fleas on the dog. 5 Jun 2019: Another vial was applied. The owner started to note fleas in the household. 3 Jul 2019: The issue is still ongoing. The dog has access to a fenced in yard. There is 1 dog and 1 cat in the household also experiencing an issue with fleas (see case 19US040375, and 19US040392). No further medical information is expected.
03-Jul-2019	UAE; 19US039075; IL; U.S.A	Species: Canine Breed: Retriever Labrador Sex: F Sex qualifier: Neutered Age: 13.00 Year(s) Weight: 60 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	28-Jun-2019	28-Jun-2019	0 Day(s)	D-C	Suspected Adverse Event: On 03 Jul 2019 an animal owner reported the following event in Kation, a 13 year old, 60 pound, female spayed, Labrador Retriever. 28 Jun 2019: The canine was administered 1 vial of FRONTLINE PLUS DOGS 45-88 LB (NO65331-5) between the shoulder blades. Within 30 minutes the canine had a seizure. 03 Jul 2019: The canine is still not acting right. The canine is not eating or drinking and is ataxic. No further information provided nor expected. UPDATE 17 Jul 2019: After further review the country assessments were changed to serious.
03-Jul-2019	UAE; 19US039107; -; U.S.A	Species: Canine Breed: Chihuahua Sex: X Sex qualifier: Mixed Age: - Weight: Unknown	3	3	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: medicated shampoo; Route: Topical / Cutaneous Was the product used ok?: Yes	15-May-2019*	15-Jun-2019	18 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 3 Jul 2019, a pet owner reported the following event for 3 Chihuahuas of further unknown signlment. Unknown Date: The dogs have been using FRONTLINE PLUS DOG 23-44 LBS (lot unkonwn) for years without any issues, and the owner applies yearly. 15 Jun 2019: The owner applied the most recent dose of FRONTLINE between the shoulders. The dogs had fleas on them at the time of application. 3 Jul 2019: The owner is still seeing fleas and reports the dogs are itching constantly. The owner bathes the dogs in a medicated shampoo once a week on unknown dates. There are 2 other dogs in the house having the same issue, see case 19US039155. The dogs go outside. No further medical information expected.
03-Jul-2019	UAE; 19US039128; IL; U.S.A	Species: Canine Breed: Retriever (Golden) Sex: F Sex qualifier: Neutered Age: 11.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	26-Jun-2019	27-Jun-2019	1 Day(s)	D-D	Suspected Adverse Event: On 3 Jul 2019, the owner reported the following event for Dallas, 11 year old, spayed female, Golden Retriever canine of unknown weight. 26 Jun 2019: One vial of FRONTLINE PLUS DOG 45-88 LBS (S61313AR) was applied between the shoulder blades. 27 Jun 2019: The dog experienced diarrhea. 28 Jun 2019*: The dog presented to the clinic. It is unknown what treatment was provided. The current status of the pet is unknown. The dog has received the product on prior unknown dates with no issue. There are 2 other dog in the household that also received the product and experienced symptoms (see case 19US039176). No further medical information is expected.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 330 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00337

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
03-Jul-2019	UAE; 19US039151; TN; U.S.A	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	10-Jun-2019	03-Jul-2019	23 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 03 Jul 2019, animal owner reported the following event for 2 cats. All signalment is unknown. 10 Jun 2019: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS CATS (Lot unknown) topically between the shoulder blades for the first time. 03 Jul 2019: The pet owner started seeing live fleas on both cats. The cats are indoor only. There are two outdoor only dogs at the home. The animal owner has not treated the environment. The cats have not been bathed. No further information expected. UPDATE 30 Jul 2019: Per the pet owner, the heaviest cat is approximately 12 pounds. 10 Jul 2019: One vial of FRONTLINE PLUS CATS was applied to each feline for a second time in the same fashion as previously described. Unknown dates: The pet owner continues to find an unknown quantity of fleas on both cats and is also noticing both cats scratching a lot. An exterminator also treated the home, though fleas are still present. Presently, the cats are continuing to get fleas inside the home. The reporter provided no information regarding the internal or external environment, but confirmed her two outdoor dogs weigh between 50 and 60 pounds and have both received FRONTLINE PLUS DOG 45-88 LBS (lot unknown) applied topically between the shoulder blades on 10 Jun 2019 and 10 Jul 2019. It's unknown if the reporter is finding any fleas on the canines. The cats are not being bathed and no treatment has been given. No further medical information expected.
03-Jul-2019	UAE; 19US039155; -, U.S.A	Species: Canine Breed: Pit Bull Sex: X Sex qualifier: Mixed Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: Hartz oatmeal shampoo; Route: Topical / Cutaneous Was the product used ok?: Yes	15-May-2019*	15-Jun-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 3 Jul 2019, a pet owner reported the following event for 2 Pitbulls of further unknown signalment. Unknown Date: The dogs have been using FRONTLINE PLUS DOG 45-88 LBS (lot unknown) for years without any issues, owner applies yearly. 15 Jun 2019: The owner applied the most recent dose of FRONTLINE between the shoulders. The dogs had fleas on them at the time of application. 3 Jul 2019: The owner is still seeing fleas and reports the dogs are itching constantly. The owner bathes the dogs in a Hartz oatmeal shampoo once a week on unknown dates. There are 3 other dogs in the house having the same issue, see case 19US039107. The dogs go outside. No further medical information expected.
03-Jul-2019	UAE; 19US039163; TX; U.S.A	Species: Canine Breed: Pug Sex: F Sex qualifier: Neutered Age: 12.00 Year(s) Weight: 13 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment /	03-Jun-2019	04-Jun-2019*	1 Day(s)	D-D	Suspected Adverse Event: On 3 Jul 2019, the owner reported the following event for Joany, 12 year, 13 pound, spayed female, Pug canine. 3 Jun 2019: One vial of FRONTLINE PLUS DOG 5-22 LBS (S63009AL) was applied between the shoulder blades to the base of the tail. Unknown date: The owner found 1 dead flea on the dog. The owner also noticed the dog itching after the application. 3 Jul 2019: The itching is still ongoing. It is unknown if any fleas are on the pet. The dog goes for walks around the neighborhood and has access to dog parks. The dog has received the product on prior unknown dates with no issue. There are no other pets in the household. No further medical information is expected.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 331 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00338

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
03-Jul-2019	UAE; 19US039168; -; U.S.A	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	vaccination program not respected) Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	01-Jul-2019*	03-Jul-2019	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: 03 Jul 2019: An owner reported the following event in two dogs of unknown signalmen indoor-outdoor dogs. 01 Jul 2019*: The groomer administered FRONTLINE PLUS DOGS (lot unknown, package unavailable)(product unsubstantiated and could not confirm for sure it was a BIAH product) typically in an unknown manner to 2 dogs for the first time.It is unknown if fleas were seen at the time of application. 03 Jul 2019: The owners are seeing an unknown amount of fleas. The groomer told the owner the product was good for 90 days on fleas. The product was not confirmed. It is unknown if the pets were bathed the same day, before or after application. No further medical information available.
03-Jul-2019	UAE; 19US039176; IL; U.S.A	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	26-Jun-2019	27-Jun-2019	1 Day(s)	D-D	Suspected Adverse Event: On 3 Jul 2019, the owner reported the following event for 2 canines (all other signalments unknown). 26 Jun 2019: One vial of FRONTLINE PLUS DOG (product unsubstantiated) (lot unknown) was applied topically at an unknown location. 27 Jun 2019: The dogs experienced diarrhea. 28 Jun 2019*: The dogs presented to the clinic. It is unknown what treatment was provided. 3 Jul 2019: The current status of the pet is unknown. The dog has received the product on prior unknown dates with no issue. There is one other dog in the household that also received a FRONTLINE product and experienced symptoms (see case 19US039128). No further medical information is expected.
03-Jul-2019	UAE; 19US039178; -; U.S.A	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	01-Jul-2019	01-Jun-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 3 Jul 2019, a pet owner reported the following event for a canine of unknown signalment. Jun 2019: The owner applied FRONTLINE PLUS DOG (product unsubstantiated)(lot unknown) and it did not work, owner seeing fleas. 1 Jul 2019: The owner applied FRONTLINE PLUS. 2 Jul 2019: The owner is seeing fleas on dog. The owner bathed dog and reapplied FRONTLINE PLUS. 3 Jul 2019: The dog still has fleas, owner saw 5 fleas on stomach. Per the owner, the dog does not go outside long enough to have fleas get on the dog and it is impossible that there is any infestation in the house. There are 2 outdoor cats that are treated with FRONTLINE PLUS CAT (lot unknown) that do not have fleas. No further medical information expected as owner became combative.
03-Jul-2019	UAE; 19US039180; NC; U.S.A	Species: Canine Breed: Alaskan Malamute Sex: U Sex qualifier: Unknown Age: -	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other	03-Jun-2019*	03-Jul-2019	30 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 3 Jul 2019, the veterinarian reported the following event for Lennon, an Alaskan Malamute of unknown signalment. 2018*: The dog began receiving monthly doses of FRONTLINE PLUS (product unsubstantiated) (lot and expiration unknown) 3 Jul 2019: The owner continues to see an unknown number of fleas on the dog.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 332 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00339

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: Unknown				products Route: Topical / Cutaneous Was the product used ok?: Yes					There are no other pets in the home. Additional details regarding the patient, FRONTLINE USE, and environment are unknown as the reporter was unable to provide details. No further information at this time.
03-Jul-2019	UAE; 19US039189; VA; U.S.A	Species: Canine Breed: Yorkshire Terrier Sex: U Sex qualifier: Unknown Age: - Weight: 8 - 22 lbs	4	4	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	23-Jun-2019	03-Jul-2019	10 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 3 Jul 2019, the owner reported the following event for 4 Yorkshire Terrier canines, weighing between 8-22 pounds (all other signalments unknown). 23 Jun 2019: One vial of FRONTLINE PLUS DOG 5-22 LBS (S60302AL) was applied between the shoulder blades. 3 Jul 2019: The dogs presented to the groomer and fleas were noted. The pets were bathed, it is unknown if the fleas are still present. The dogs have received the product on a year round basis for the past few years (2017*). The dog have access to a fenced in and treated backyard. No further medical information is expected.
03-Jul-2019	UAE; 19US039204; FL; U.S.A	Species: Canine Breed: Yorkshire Terrier Sex: F Sex qualifier: - Age: 9.00 Month(s) Weight: 6.5 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	03-Jul-2019	03-Jul-2019	0 Day(s)	D-D	Suspected Adverse Event: On 3 Jul 2019, the owner reported the following event for Pebbles, a 9 month old (born approx. 1 Oct 2018*), 6.5 pound, non-pregnant non-lactating intact female, Yorkshire Terrier. 3 Jul 2019: Started on 1 vial of FRONTLINE PLUS DOG 5-22 LBS (S61006AL) topically between the shoulder blades, by the owner, for the first time. Approximately 15 minutes later, the owner felt that the dog's heartrate was fast and that the dog was nervous and skiddish. The dog was not seen by a veterinarian or given any treatment. No further medical information expected.
03-Jul-2019	UAE; 19US039212; -; U.S.A	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: F Sex qualifier: Neutered Age: 6.00 Year(s) Weight: 5 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	30-Jun-2019	30-Jun-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: 03 Jul 2019: An owner reported the following event in Smokey; a 6 year old, 5 pound, spayed, female, Domestic Shorthair, indoor cat. 21 Jun 2019: The owner applied one tube FRONTLINE PLUS CATS (lot unknown, package unavailable) topically in an unknown manner for the first time. Fleas were not seen at the time of application. 30 Jun 2019: The owner saw the cat itching but never saw fleas. The owner took the cat to the veterinarian who said they might have ear mites. The owner believes the itching is due to fleas. No further medical information available.
03-Jul-2019	UAE; 19US039217; -; U.S.A	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products	15-Jun-2019	30-Jun-2019*	15 Day(s)	D-D	Suspected Adverse Event: 03 Jul 2019: An owner reported the following event an unknown indoor-outdoor cat of unknown signalment. 15 Jun 2019: The owner applied one tube FRONTLINE PLUS CATS (lot unknown, package unavailable) topically in an unknown manner for the first time. It is unknown if fleas were seen at the time of application. 30 Jun 2019*: The owner saw the cat itching but never saw fleas.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 333 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00340

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Route: Topical / Cutaneous Was the product used ok?: Unknown to Company					The owner believes the itching is due to fleas. No further medical information available.
03-Jul-2019	UAE; 19US039230; MN; U.S.A	Species: Canine Breed: Shiba Inu Sex: F Sex qualifier: Neutered Age: 7.00 Month(s) Weight: 17 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	02-Jul-2019	02-Jul-2019	0 Day(s)	D-D	Suspected Adverse Event: On 3 July 2019, the owner reported the following event for Asta, 7 months, 17 pounds, spayed female, Shiba Inu. 2 July 2019: One vial of FRONTLINE PLUS DOG 5-22 LBS (S61006AL) was applied between the shoulder blades, by the pet owner. Two hours after application the dog vomited two times. 3 July 2019: The dog continued to vomit an additional three times. The dog is also lethargic. The dog has not been seen by a veterinarian and no treatment has been provided at this time. This was the first time receiving FRONTLINE PLUS. No further medical information is expected.
03-Jul-2019	UAE; 19US039259; NY; U.S.A	Species: Canine Breed: Retriever (Labrador, Black) Sex: F Sex qualifier: Neutered Age: 4.00 Year(s) Weight: 53 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	28-May-2019	28-Jun-2019	31 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 3 Jul 2019, the pet owner reported the following event for Annie, a 4 year old, 53 pound, spayed female, Black Labrador Retriever. 28 May 2019: The patient got her monthly dose of FRONTLINE PLUS DOG 45-88 LBS(S62111AL). 28 Jun 2019: The owner noticed one tick on the animal when the owner was going to apply the dose of FRONTLINE PLUS. The owner stated she applies FRONTLINE correctly, does not give other products at the same time, and the dog has not been bathed recently. It was just one tick and the owner does not know if it was still alive. She stated she plucked it off and burned it. She is not seeing ticks in the home or on herself. The dog does have access to a fenced in yard. The owner has not noticed any strays or uptake in wild animals recently. The animal's current condition is recovered. The dog is the only animal in the house household, and has no prior reactions noted. The owner stated the dog has been using FRONTLINE since about 2016*. No further medical information expected.
03-Jul-2019	UAE; 19US039265; -; U.S.A	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	01-Jul-2019*	03-Jul-2019*	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 03 Jul 2019, the pet owner reported the following event for Toto, an unknown canine of further unknown signalment. 01 Jul 2019*: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS DOG (product unsubstantiated) (lot unknown) topically between the shoulder blades for the first time. 03 Jul 2019*: The pet owner found an unknown quantity of fleas on the dog. Owner called stating that a case had been created. No case could be found. No further medical information expected.
08-Jul-2019	UAE; 19US039332; FL; U.S.A	Species: Canine Breed: Chinese Crested	3	3	0	Product used: FIPRONIL 10%/S	17-Jun-2019	24-Jun-2019*	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 8 Jul 2019, a pet owner reported the following event for Lee, Walker, and J.D., 10-14 years old, intact male Chinese Crested canines.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 334 of 867

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

v1.2

ED_005739D_00014390-00341

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex: M Sex qualifier: - Age: 10.00 Year(s) Weight: 11 lbs				METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes					2010*: The dogs began receiving monthly applications of FRONTLINE PLUS DOG 5-22 LBS (Lot Unknown) year round, topically between the shoulder blades. 17 Jun 2019: The dogs were bathed and then received the most recent application of FRONTLINE after they were completely dry. 24 Jun 2019*: The pet owner noticed a few live fleas on the all of the dogs. The pet owner has continued to see an occasional flea on the dogs periodically. The pet owner is finding an occasional live flea on the couch as well as flea dirt. The pet owner is not getting bit. The dog's get a bath once a month. The yard is small and fenced in. No further medical information expected.
08-Jul-2019	UAE; 19US039339; MD; U.S.A	Species: Canine Breed: Poodle (Miniature) Sex: F Sex qualifier: Neutered Age: 12.00 Year(s) Weight: 13 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-Apr-2019*	07-Jul-2019	5 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 8 Jul 2019, a pet owner reported the following event for Mollie, a 12 year old, 13 pound, spayed female Miniature Poodle. 2008*: The dog began receiving monthly applications of FRONTLINE PLUS DOG 5-22 (Lot Unknown) topically between the shoulder blades. The dog receives the applications seasonally from Apr to Oct. 1 Apr 2019*: The dog received an application of FRONTLINE PLUS DOG 5-22 LBS (S60302AL). 15 May 2019*: The pet owner noticed a few live fleas on the dog. 24 Jun 2019*: The pet owner sprayed the yard with an insect repellent where the dog walks. 1 Jul 2019*: The pet owner sprayed the house with RAID insect repellent. 2 Jul 2019: The dog received 1 application of FRONTLINE. 7 Jul 2019: The groomer came to the house and noticed a few live fleas on the dog. There are no other pets in the home. The pet owner did not notice fleas after the Apr application of FRONTLINE. The owner lives in the country but the dog does not go far from the house. The pet owner is vacuuming daily and is washing the dog's bedding once a week. No further medical information expected.
22-Aug-2019	UAE; 19US039345; Texas; U.S.A	Species: Canine Breed: - Sex: - Sex qualifier: - Age: - Weight: -	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	21-Jun-2019	01-Jul-2019	N/A	N/A	Suspected Lack of Efficacy Claim: On 01 Jul 2019 an animal owner reported the following event in 2 dogs. All other signalment unknown. 21 Jun 2019: The 2 dogs were each administered 1 vial of FRONTLINE PLUS 5-22 LB. There were fleas on animals and in home at time of administration. 01 Jul 2019: The animal owner is still seeing fleas. There is 1 cat in the household reported in case and 1 canine reported in case that are on FRONTLINE PLUS. No further information provided nor expected. UPDATE 08 Jul 2019: Case 19US039345 made is error and is a duplicate of case 19US038139. Case 19US039345 to be changed to inquiry. PV Works is not allowing me to change to inquiry.
08-Jul-2019	UAE; 19US039350; INDIANA; U.S.A	Species: Canine Breed: Border Collie Sex: F Sex qualifier: Neutered Age: 14.50 Year(s) Weight: 53 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical /	01-Jul-2019	07-Jul-2019	6 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 08 Jul 2019 an animal owner reported the following event in Heidi, a 14.5 year, 53 pound, male neutered, a border collie mix. 2015*: The canine started receiving FRONTLINE PLUS DOG 45088 LBS (S63106AX) monthly. 01 Jul 2019: The canine was applied FRONTLINE PLUS in between the shoulder blades. No fleas seen at time of administration. 07 Jul 2019: The animal owner saw one flea on the canine.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 335 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00342

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Cutaneous Was the product used ok?: Yes					There are no other pets in the household. The canine has minimal access to the outdoors. The canine is currently on Cytropoint for allergies and Mobiflex for arthritis. No further information provided more expected.
08-Jul-2019	UAE; 19US039355; CA; U.S.A	Species: Canine Breed: Terrier Breeds (500 Series) Sex: M Sex qualifier: Neutered Age: 7.00 Year(s) Weight: 28 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-Jul-2016*	05-Jul-2019*	4 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 8 Jul 2019, a pet owner reported the following event for Oliver, a 7 year old, 28 pound, neutered male Terrier mix. 2016*: The dog began receiving monthly year round applications of FRONTLINE PLUS DOGS 23-44 LBS (Lot Unknown) topically between the shoulder blades. 1 Jul 2019*: The dog received 1 application of FRONTLINE. 5 Jul 2019*: The pet owner noticed a few live fleas on the dog. The pet owner did not provide any additional details once I explained how the product worked and what is required for the guarantee. No further medical information expected.
08-Jul-2019	UAE; 19US039357; SC; U.S.A	Species: Canine Breed: Chihuahua Sex: M Sex qualifier: Neutered Age: 11.00 Year(s) Weight: 12 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-May-2019	15-May-2019	2 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 8 Jul 2019, the pet owner reported the following event for Troy, an 11 year old, 12 pound, neutered male Chihuahua. 2017*: the dog began receiving monthly doses of FRONTLINE PLUS DOG 0-22 LBS (lot and expiration unknown) year-round with the most recent applications on 1 May 2019, 1 Jun 2019 and 1 Jul 2019. 15 May 2019*: The owner noted over 10 live fleas on the dog. The owner has continued to observe more than 10 live fleas on the dog. No fleas have been seen in the home and there are no other animals in the home. The dog was not bathed after receiving FRONTLINE PLUS and spends most of his time indoors. No further medical information expected.
08-Jul-2019	UAE; 19US039360; AL; U.S.A	Species: Canine Breed: Canine various breeds Sex: U Sex qualifier: Unknown Age: - Weight: 44 - 45 lbs	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Low dose)	06-Apr-2019*	20-Apr-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 8 Jul 2019 the pet owner reported the following event for 2 canines: an Unknown 44-45 pound pointer mix and an unknown 44-45 pound German Shepherd dog and Welsh Corgi mix. All other signalments are unknown. *2007: The owner began applying 1 vial of FRONTLINE PLUS DOG 23-44 LBS (UNKNOWN) to the skin between the shoulder blades on a monthly and year round basis. *6 Apr 2019: The owner applied another dose. *20 Apr 2019: The owner began noticing fleas on the dogs. *6 May 2019: The owner applied another dose. *6 Jun 2019: The owner applied another dose *24 Jun 2019: The owner applied the most recent dose. 4 Jul 2019: The owner continued seeing 5-6 fleas consistently and flea bombed 1 room in the house. There are no other pets in the home. The dogs are mainly indoors but do go outside into a fenced in grassy yard with a mulched garden. The owner is noticing small amounts of indoor flea activity. It is unknown if the dogs get baths or have a skin condition. No further medical information expected.
08-Jul-2019	UAE; 19US039361; CA; U.S.A	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: F	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON	07-Jul-2019	07-Jul-2019	0 Day(s)	D-D	Suspected Adverse Event : On 8 Jul 2019, the owner reported the following event for Phoebe, 6 year old, female spayed, 6 pound, Domestic Shorthair. 7 Jul 2019: One vial of the FRONTLINE PLUS CATS (L40505AX) was applied topically in between the shoulder blades by the owner.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 336 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00343

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: Neutered Age: 6.00 Year(s) Weight: 6.0 lbs				Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes					Within hours the pet started vomiting, per owner he thinks the cat may have ingested the product. No treatment has been given to the pet as of now. The cat has not been presented to the clinic. The pet has been on FRONTLINE prior starting at an unknown date. No further medical information is expected.
08-Jul-2019	UAE; 19US039363; MAINE; U.S.A	Species: Canine Breed: Canine (unknown) Sex: M Sex qualifier: Neutered Age: 4.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	24-Jun-2019	08-Jul-2019	2 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 08 Jul 2019 an animal owner reported the following event in Jackson, a 4 year old, male neutered mix breed dog. All other signalment unknown. 24 Jun 2019*: The canine was administered 1 vial of FRONTLINE PLUS 45-88LB (P61701AR) 25 Jun 2019: The canine rolled in feces and was hosed off 08 Jul 2019: The animal owner reports seeing ticks on the canine. No further information provided nor expected.
08-Jul-2019	UAE; 19US039364; -, U.S.A	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: 5 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	05-Jun-2019	02-Jul-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 8 Jul 2019, the owner reported the following event for a 5 pound canine (all other signalments unknown). 5 Jun 2019: First vial of FRONTLINE PLUS DOG 5-22 LBS (S61006AL) was applied topically between the shoulder blades by the owner. No fleas seen on dog prior to the application. 1 Jul 2019: Most recent dose of FRONTLINE was applied. 2 Jul 2019*: The owner started seeing about 20 fleas on the dog. The owner is not seeing fleas in the home. The dog goes outside onto a porch that has a crawl space underneath. No further medical information expected.
08-Jul-2019	UAE; 19US039368; PA; U.S.A	Species: Feline Breed: Norwegian Forest Cat Sex: F Sex qualifier: Neutered Age: 10.00 Year(s) Weight: 17 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	03-Jul-2019	03-Jul-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 8 Jul 2019, a pet owner reported the following event for Edna, a 10*year old, 17 pound, spayed female Norwegian Forest Cat. 3 Jun 2019: The cat received 1 application of FRONTLINE PLUS CATS (S40606AW) topically between the shoulder blades in one spot for the first time. The pet owner did not notice any fleas prior to application. 3 Jul 2019: The pet owner noticed that the cat was grooming a lot and biting at her hind end. She noticed 5 live fleas on the cat's belly. The cat received 1 application of FRONTLINE. The pet owner has had a few fleas jump on her ankles. There are no other pets in the household and the cat is indoor/outdoor. The cat likes to sleep under bushes outside. The pet owner has used Advantage in the months prior to FRONTLINE for years without any issues. No further medical information expected.
08-Jul-2019	UAE; 19US039388; -, U.S.A	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier:	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON	28-May-2019	27-Jun-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 08 Jul 2019 an animal owner reported the following event in a dog. All other signalment is unknown. 2017*: The canine started receiving monthly doses of FRONTLINE PLUS 5-22 LB (lot S61006AL).

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 337 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00344

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Unknown Age: - Weight: Unknown				Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes					28 May 2019: The canine was administered 1 dose of FRONTLINE PLUS. 27 Jun 2019: The canine presented for itchy skin. At time of exam the vet was reported to see fleas. The canine was diagnosed with flea allergy dermatitis and a yeast infection. The canine was treated with an unspecified antibiotic and steroid. 28 Jun 2019: The canine was administered FRONTLINE PLUS. Fleas were seen at time of administration. 08 Jul 2019: The animal owner is seeing fleas on the canine. There are 2 cats in the household that are currently on FRONTLINE PLUS that are reported in case 19US039409. The canine has access to outdoors. No further information provided nor expected.
08-Jul-2019	UAE; 19US039391; -, U.S.A	Species: Canine Breed: Border Collie Sex: F Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	03-Jul-2019	08-Jul-2019	5 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 08 Jul 2019, a pet owner reported the following event for a female Border Collie, of further unknown signalment. 01 Jun 2019: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS DOG (product unsubstantiated) (lot unknown). 02 Jun 2019*: The owner found an unknown number of dead and live ticks. 03 Jul 2019: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS DOG (product unsubstantiated) (lot unknown). 08 Jul 2019: The owner found an unknown number of dead and live ticks. The owner and dog are currently in Minnesota. Owner was seeking product information, did not intend to report. No further medical information expected.
08-Jul-2019	UAE; 19US039395; -, U.S.A	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	01-Jul-2019*	01-Jul-2019*	0 Day(s)	D-D	Suspected Adverse Event: On the 8 Jul 2019, a pet owner reported the following event for a canine of unknown signalment. Jul 2019*: The owner applied 1 dose of FRONTLINE PLUS DOG (Unsubstantiated) (unknown lot number) topically to the dog in an unknown site. An unknown amount of time later the dog began itching all over the body. The symptom is ongoing. The dog has not presented to the clinic and has not received any treatment. The dog has had this product in the past since an unknown date without any issues. Further details are unknown as the owner declined to give a report.
08-Jul-2019	UAE; 19US039409; -, U.S.A	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	28-Jun-2017*	28-Jun-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 08 Jul 2019 an animal owner reported the following event in two felines. All other signalment is unknown. 2017*: The two felines started receiving monthly doses of FRONTLINE PLUS CATS (lot S41108AW). 28 Jun 2019: The felines were was administered FRONTLINE PLUS. Fleas were seen at time of administration. 08 Jul 2019: The animal owner is seeing fleas on the felines. There is a canine in the household that is currently on FRONTLINE PLUS that is reported in case 19US039388. No further information provided nor expected.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 338 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00345

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
08-Jul-2019	UAE; 19US039421; -; U.S.A	Species: Canine Breed: Shih Tzu Sex: M Sex qualifier: Unknown Age: 12.00 Month(s) Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	28-Jun-2019	06-Jul-2019	8 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 8 Jul 2019, the pet owner reported the following event for a 12 month old*, less than 16 pound, male, Shih Tzu of further unknown signalment. 28 Jun 2019: The canine received one vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) applied topically starting between the shoulder blades and stopping mid-back, for the first time. 1 Jul 2019: A foster dog was introduced into the home at which time, no fleas were seen on him/her. Before being introduced into the reporter's home, the foster dog was treated with an unknown flea control product given said canine had been covered in fleas when rescued. 6 Jul 2019: Following onset of incessant pruritus, the reporter then observed approximately two living fleas and approximately two deceased fleas on her Shih Tzu. 7 Jul 2019: The foster dog was adopted and has since left the reporter's home. Presently, she is not finding fleas in her home, but has since washed all of her bedding. She also continues to find a couple of fleas on her Shih Tzu. There are two other dogs in the home who are also receiving FRONTLINE PLUS and are experiencing the same problems. Please see cases 19US040065 and 19US040066. All three resident dogs go outside in the yard to go to the bathroom. The reporter described the yard as a wooded area, but then said it was not really a wooded area. No further clarification could be obtained other than the dogs also have access to an area with wood chips, a row of trees that divide her yard from her neighbor's yard, and spend time at the dock. No further medical information expected.
08-Jul-2019	UAE; 19US039439; NY; U.S.A	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: F Sex qualifier: Neutered Age: 12.00 Year(s) Weight: 14.0 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	05-Jul-2017*	06-Jul-2019	1 Day(s)	D-D	Suspected Adverse Event: On 08 Jul 2019, the veterinary clinic staff reported the following event for Sweetie, a 12 year old (born 26 Aug 2006), 14.0 pound, spayed female Domestic Shorthair. 05 Jul 2019: She received a FRONTLINE PLUS FOR CATS (P40414AW) one dose applied topically between the shoulders. 06 Jul 2019: She began experiencing alopecia at the application site. 07 Jul 2019: She presented to the veterinary clinic. No diagnostics or treatments were performed. Her current condition is ongoing. She previously received a FRONTLINE PLUS monthly for several years with no adverse effects noted. No further medical information expected.
08-Jul-2019	UAE; 19US039467; CA; U.S.A	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	02-Jul-2019	07-Jul-2019	5 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 08 Jul 2019, Animal owner reported the following event for her 2 dogs. All signalment is unknown. 02 Jul 2019: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS DOG 5-22 LBS (Lot unknown) topically between the shoulder blades for the first time. 07 Jul 2019: The pet owner found 7 fleas total on both dogs. There are no other animals in the home. The dogs have not been bathed. The environment has not been treated. Both dogs are indoor/ outdoor dogs. No further information expected.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 339 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00346

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
08-Jul-2019	UAE; 19US039478; NM; U.S.A	Species: Canine Breed: Boston Terrier Sex: M Sex qualifier: Neutered Age: 24.00 Month(s) Weight: 23.5 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	03-Jul-2019	06-Jul-2019*	3 Day(s)	D-C	Suspected Adverse Event: On 8 Jul 2019, the clinic staff reported the following event for Mischa, a 2 year old (born 1 Jul 2017), 23.5 pound, neutered male Boston Terrier. Unknown date: The dog received an unknown dose of FRONTLINE PLUS (product unsubstantiated) and had an unknown reaction. Further details regarding the event are unknown as the reporter did not have additional details to share at the time of call. No further information at this time. UPDATE 8 Jul 2019: Per the pet owner: 3 Jun 2019*: One vial of FRONTLINE PLUS DOG 23-44 LBS (S61009AL) was applied topically between the shoulder blades for the first time without any issues. 3 Jul 2019: One vial of FRONTLINE PLUS was applied topically between the shoulder blades that evening. On approximately the same date, Mischa stayed with the reporter's mother while he was out of town. 6 Jul 2019*: When the reporter returned home, he saw his mother towel dry Mischa because it was raining. While being dried, the canine yelped. Upon closer inspection, the reporter noticed he had generalized urticaria and that much of the hair coat at FRONTLINE PLUS application site had fallen out. The remaining hair at the site appeared to be "lifted off of the skin", though the reporter was unable to further describe the condition of the remaining hair at the application site. Before treating with Benadryl, he also noticed localized scabbing and active bleeding at the product application site. 7 Jul 2019: When Mischa presented to the veterinarian for his symptoms, he also had an elevated body temperature. His temperature could not be confirmed by the reporter, though the canine was subsequently treated with dexamethasone-SP, Benadryl, and a 14 day course of cephalexin. The veterinarian also sent the canine home with TropiClean shampoo which he was bathed in that day in an effort to remove the FRONTLINE PLUS. 8 Jul 2019: Mischa was much improved, but not yet recovered and remains under treatment. No further medical
08-Jul-2019	UAE; 19US039527; -; U.S.A	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: 34 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	26-Jun-2019*	01-Jul-2019*	5 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 8 Jul 2019, the pet owner reported the following event for a 34 pound dog of further unknown signalment. Unknown date: The patient began receiving FRONTLINE PLUS DOG 23-44 LBS (lot unknown). Unknown date: It is unknown if the owner saw fleas or ticks. It is unknown if the owner noticed fleas/ticks prior to application. It is unknown if the FRONTLINE is applied correctly, or if the animal has been on FRONTLINE prior to this dose. The animal's outside and inside environments are unknown. It is unknown if any other products are given along with the FRONTLINE. The animal's current condition is unknown. There a total number of animals in the household is also unknown. The owner was driving at this time and could not complete inquiry. No further medical information expected. UPDATE 09 Jul 2019: 26 Mar 2019*: The dog received an unknown flea and tick control treatment at the veterinarian. 26 Jun 2019*: The pet owner applied 1 full vial of FRONTLINE PLUS DOG 23-44 LBS (lot unknown) between the shoulder blades of the dog for the first time.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 340 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00347

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											01 Jul 2019*: The owner saw fleas on the dog. The dog has allergies. Owner was not receptive. Call was ended before further information could be obtained. No further medical information expected.
07-Jul-2019	UAE; 19US039528; AL; U.S.A	Species: Canine Breed: Medium crossbred (10 - 20 Kg) Sex: F Sex qualifier: Neutered Age: 13.00 Year(s) Weight: 40 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	04-Jul-2019	05-Jul-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 7 Jul 2019, the following event was reported to Safety Call International (SCI) by the pet owner for Peaches, a 40 pound, 13 year old, spayed female crossbred dog. 4 Jul 2019: Owner applied FRONTLINE PLUS DOG 23-44 LBS (unsubstantiated) (lot unknown) in an unknown manner in an unknown location. Owner did see fleas on her dog before application, and Peaches was scratching before application. Peaches is still scratching. Owner is no longer seeing fleas on the dog. Peaches is an outdoor only dog. Owner does not have the package and does not know which Frontline product she used. No further medical information expected.
08-Jul-2019	UAE; 19US039534; SC; U.S.A	Species: Canine Breed: Dachshund Sex: F Sex qualifier: Neutered Age: 10.00 Year(s) Weight: 15 - 16 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	01-Jun-2009	08-Jul-2019	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 8 Jul 2019, the owner reported the following event for Daisy, a 15 pound, 10 year old*, spayed female Dachshund. 1 Jun 2009*: Daisy started on FRONTLINE PLUS DOG 5-22 LBS (S60401AX) via unknown route and location. 1 Jul 2019: The most recent dose was applied. 8 Jul 2019: The owner reports still seeing fleas on the dog. He also reported that Daisy has become increasingly pruritic and has started biting at her rear end. Fleas were not noticed prior to most recent application. Daisy has been on the product year round since Jun 2009* and has never had an issue. There are no other dogs in the home and she is considered to be an indoor dog, besides walks and potty breaks. No further information at this time.
05-Jul-2019	UAE; 19US039538; SC; U.S.A	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: 11.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	05-Jul-2019	05-Jul-2019	0 Day(s)	D-D	Suspect Adverse Event: On 05 Jul 2019, an owner reported the following event, through Safety Call International (SCI), for an 11 year old (05 Jul 2008*), feline, of further unknown signalment. 05 Jul 2019: One vial of FRONTLINE PLUS FOR CATS (lot unknown) was applied between the shoulder blades on the cat. 4-5 hours later the cat began to run around the house and is licking the area of application and may have ingested some of the product. Owner wiped some of the product off with a paper towel. Owner could not find lot number and could not finish the call due someone being at her door. No further medical information expected.
08-Jul-2019	UAE; 19US039563; IL; U.S.A	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical /	04-Jun-2019	05-Jul-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 8 July 2019, the owner reported the following event for a male, Domestic Shorthair (crossbreed) (all other signalments unknown). 4 June 2019: The cat started using the FRONTLINE PLUS on a monthly basis, seasonal use. 4 July 2019: The most recent vial of FRONTLINE PLUS CATS (lot unknown) was applied between the shoulder blades, by the pet owner. 5 July 2019*: The cat had 3 to 4 fleas.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 341 of 867

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

v1.2

ED_005739D_00014390-00348

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Cutaneous Was the product used ok?: Yes					The cat does not get bathed. The owner is not seeing any flea activity in the home. The cat is indoor/outdoor. No further medical information is expected. UPDATE 12 July 2019: Checked No more information expected box. No further information expected.
08-Jul-2019	UAE; 19US039575; -; U.S.A	Species: Canine Breed: Spaniel (Cocker) Sex: F Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	01-Jul-2019*	05-Jul-2019*	4 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 08 Jul 2019, the pet owner reported the following event for a female Cocker Spaniel of further unknown signalment. 01 Jul 2018*: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS DOG(product unsubstantiated) (lot unknown) topically between the shoulder blades for the first time that year. 01 Jul 2019*: The owner applied the most recent dose of FRONTLINE PLUS to the dog. 05 Jul 2019*: Dog was at the groomer and the groomer saw live fleas and flea dirt. Owner disconnected before more information could be received. No further medical information expected.
08-Jul-2019	UAE; 19US039582; NC; U.S.A	Species: Canine Breed: Pomeranian Sex: M Sex qualifier: - Age: 8.00 Year(s) Weight: 8.5 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: Dawn; Olive Oil; Unknown Bordetella Vaccine; Route: Topical / Cutaneous Was the product used ok?: Yes	27-Jun-2019	07-Jun-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 08 Jul 2019, the pet owner reported the following event for Roo Roo, a 8.5 pound, 8 year old (03 Dec 2010), intact male, Pomeranian. 2011*: The dog began receiving FRONTLINE PLUS DOG 5-22 LBS (S61006AL) monthly. 07 Jun 2019*: The dog presented to the veterinarian for an unknown bordetella vaccine. 08 Jun 2019*: Owner saw 10 fleas on the dog. The owner bathed the dog in Dawn and rubbed olive oil on the dogs' skin. 09 Jun 2019*: The dog presented to the groomer and its' coat was shaved down. 27 Jun 2019: The most recent dose of FRONTLINE was given by the owner applying 1 full vial between the dogs' shoulder blades. 07 Jul 2019*: The owner continued to see fleas. 08 Jul 2019: The dog received a dose of NEXGARD (product unsubstantiated) (lot and expiration unknown). The owner stated the dog is pad trained and indoor only. Owner lives in the country and they constantly treat their environment. The owner washes the dogs' towel daily and threw out its' bedding. There is no carpet in the home. The owner thinks the dog got fleas from the veterinarian. Owner says other people in the area are having flea problems as well. No further medical information expected.
08-Jul-2019	UAE; 19US039596; AZ; U.S.A	Species: Canine Breed: Greyhound Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-Jul-2019	08-Jul-2019	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 08 Jul 2019 an animal owner reported the following event in 2 Greyhounds. All other signalment unknown. 01 Jul 2019: Both of the canines were each applied 1 vial of FRONTLINE PLUS 45-88 LBS (S62111AL) for the first time. There were was an unspecified number of ticks on both canines at the time of administration. 08 Jul 2019: The canines still have ticks. No further information provided nor expected.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 342 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00349

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
08-Jul-2019	UAE; 19US039599; WA; U.S.A	Species: Canine Breed: Yorkshire Terrier Sex: M Sex qualifier: Neutered Age: 13.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	05-Jul-2019	06-Jul-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 8 Jul 2019, the pet owner reported the following event for a Yorkshire and Pomeranian mix of unknown signalment. 7 Jul 2019: After observing less than 10 live fleas on the dog, the owner applied 1 dose of FRONTLINE PLUS to the dog between the shoulder blades for the first time. 8 Jul 2019: More than 24 hours after application, the owner continued to see less than 10 fleas on the dog. There are no other animals in the home. The dog spends most of his time indoors but goes outside in a grass yard occasionally. The dog was not bathed after FRONTLINE PLUS application. NO further medical information expected. UPDATE 10 Jul 2019: Per conversation with animal owner: The animal owner reported the following event in Gus, a 13 year old, male neutered, Yorkshire Terrier/ Pomeranian. 05Jul 19 The canine was administered 1 vial of FRONTLINE PLUS 5-22LB between the shoulder blades for the first time. There were no fleas seen, but possible flea dirt was seen at time of application. 06 Jul 19: The animal owner saw fleas. The animal owner washed bedding and combed out the fleas. 09 Jul 2019: The animal owner applied 1 vial of FRONTLINE PLUS 5-22 LBS inbetween the canine's shoulder blades. 10 JUL 2019: The animal owner stated that she is no longer seeing fleas on canine. The canine was reported to be on Advantage prior to the FRONTLINE PLUS administration, but it had been months since last dose was administered. The canine has a preexisting condition of being paralyzed in the hindend. At the time of the call, the animal owner noted that she was confused by the directions for application. It states above the skin and on the skin. The animal owner thinks that we need to make the directions more clear. No further information provided nor expected.
08-Jul-2019	UAE; 19US039600; CA; U.S.A	Species: Canine Breed: Retriever (Labrador, Yellow) Sex: M Sex qualifier: - Age: 5.00 Year(s) Weight: 100 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: Shampoo; Route: Topical / Cutaneous Was the product used ok?: Yes	05-Jul-2019	06-Jul-2019	1 Day(s)	D-D	Suspected Adverse Event: On 8 Jul 2019, the owner reported the following event for Remington, 5 year old, 100 pound, intact male, Yellow Labrador Retriever canine. 4 Jul 2019: The owner bathed the pet with unknown shampoo. 5 Jul 2019: One vial of FRONTLINE PLUS DOG 89-132 LBS (P61809AR) was applied between the shoulder blades for the first time this year. 6 Jul 2019: The dog experienced excessive pruritus. The dog was bleeding all over his neck, jaw, and face due to itching. The owner treated with Benadryl. 8 Jul 2019: The dog presented to the clinic. The attending veterinarian treated with unknown antibiotic, anti inflammatory, and topical ointment. The current status of the pet is unknown. The dog has received the product seasonally since 2014* with no issue. There is one other dog in the household that also experienced symptoms (see case 19US039619). No further medical information is expected.
08-Jul-2019	UAE; 19US039609; IA; U.S.A	Species: Feline Breed: Domestic Shorthair (Crossbreed)	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE	06-Jul-2019	06-Jul-2019	0 Day(s)	D-C	Suspected Adverse Event: On the 8 Jul 2019, a pet owner reported the following event for Orange Cat, a 10.8 pound, 2 year old, neutered male, Domestic Shorthair. 6 Jun 2019: The cat started on monthly FRONTLINE PLUS CATS

N/A signifies the information for this field is either not available or not applicable

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

Report printed on 25-Oct-2019 at 8:39:59PM

*indicates Approximate date or weight

Page 343 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00350

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex: M Sex qualifier: Neutered Age: 2.00 Year(s) Weight: 10.8 lbs				12% SPOT ON Other products used: Unknown Rabies; Unknown Distemper; Route: Topical / Cutaneous Was the product used ok?: Yes					(J40704AW), with 1 dose applied topically between the shoulder blades by the pet owner without any issues. 2 Jul 2019: The cat was vaccinated by the veterinarian with an unknown Rabies and Distemper vaccine with 1 ml, SC, in an unknown site by the veterinarian. 6 Jul 2019: The owner administered the most recent dose of FRONTLINE PLUS in the morning. Later that night the cat ran and hid in the basement. 7 Jul 2019: The cat was still hiding but now also had weakness in the whole right side of the body. The right front paw is the worst, the third eyelid was protruded and he had a staggered gait. The cat presented to the emergency clinic where they performed a physical exam and recommended additional diagnostics to properly diagnose but the pet owner declined. The cat was not treated. 8 Jul 2019: The cat is getting better on his own without any treatment. He continues to have the staggered gait and the weakness but it is not as prominent as what he had on the 7 Jul 2019. No further medical information is expected.
08-Jul-2019	UAE; 19US039619; CA; U.S.A	Species: Canine Breed: Retriever Labrador Sex: F Sex qualifier: Neutered Age: 7.00 Year(s) Weight: 114 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	05-Jul-2019	08-Jul-2019	3 Day(s)	D-D	Suspected Adverse Event: On 8 Jul 2019, the owner reported the following event for Maggie, 7 year old, 114 pound, spayed female, Labrador Retriever canine. 5 Jul 2019: One vial of FRONTLINE PLUS DOG 89-132 LBS (P61809AR) was applied between the shoulder blades. 8 Jul 2019: The dog experienced bloody bumps on her head. The pet did not present to the clinic and no treatment was provided. Symptoms are still ongoing. The dog has received the product seasonally since 2012* with no issue. There is one other dog in the household that also experienced symptoms (see case 19US03960). No further medical information is expected.
08-Jul-2019	UAE; 19US039634; -, U.S.A	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	14-Jun-2019	05-Jul-2019*	3 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 08 Jul 2019, the pet owner reported the following event for an unknown canine of further unknown signalment. 14 May 2019* and 14 Jun 2019: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS DOG (product unsubstantiated) (lot unknown) topically between the shoulder blades. 05 Jul 2019*: The owner saw live fleas on the dog. The owner was not receptive and disconnected before further information could be obtained. No further medical information expected.
08-Jul-2019	UAE; 19US039642; -, U.S.A	Species: Feline Breed: Calico Sex: F Sex qualifier: - Age: 5.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical /	08-Jul-2019*	08-Jul-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 8 Jul 2019, the owner reported the following event for Baby, an approx. 5 year old, non-pregnant non-lactating intact female, Calico. 8 Jul 2019: 1 vial of FRONTLINE PLUS CATS (S41103AW) was applied topically between the shoulder blades, by the owner. Right away, the cat went away to hide and was not eating. The owner is not sure if she has used the product before. The symptoms are ongoing. No further medical information expected. Update 17 Jul 2019: Per internal review the case is actually a Suspected Adverse Event. No further information is expected.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 344 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00351

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Cutaneous Was the product used ok?: Yes					
08-Jul-2019	UAE; 19US039657; CA; U.S.A	Species: Canine Breed: Poodle (Toy) Sex: F Sex qualifier: Neutered Age: 14.00 Year(s) Weight: 8.0 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: AFOXOLANER 11.3 MG CHEWABLE TABLETS; Route: Topical / Cutaneous Was the product used ok?: Yes	08-May-2019*	15-Jun-2019*	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 08 Jul 2019, the animal owner reported the following event for Hazel, a 14 year old*, 8.0 pound, spayed female Toy Poodle. 08 May 2019* and 08 Jun 2019*: She received FRONTLINE PLUS DOG 5-22 LBS (lot and expiration unknown) one dose applied topically between the shoulders. 15 Jun 2019*: The owner noticed a small amount of fleas on the canine. She began experiencing pruritus. She has not presented to the veterinary clinic. 05 Jul 2019: She received NEXGARD (11.3 MG) (lot and expiration unknown) one chew administered orally for the first time. She did not present to the veterinary clinic. Treatments were initiated with weekly bathing in an unknown flea shampoo. Her current condition is ongoing. There are no other pets in the household. She has previously received FRONTLINE PLUS monthly, seasonally for an unknown length of time with no adverse effects noted. No further medical information expected.
08-Jul-2019	UAE; 19US039667; FL; U.S.A	Species: Canine Breed: Lhasa Apso Sex: F Sex qualifier: - Age: 11.00 Year(s) Weight: 14.0 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	15-Jan-2019	15-Apr-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 08 Jul 2019, the animal owner reported the following event for Princess, a 11 year old*, 14.0 pound, intact, non-pregnant, non-lactating female Lhasa Apso. 15 Jan 2019 through 15 Jun 2019: She received FRONTLINE PLUS DOG 5-22 LBS (lot and expiration unknown) one dose applied topically monthly between the shoulders. 15 Apr 2019*: The owner noticed a small amount of fleas on the canine. She began experiencing pruritus. The owner began bathing the canine twice monthly with Dawn dish soap. The owner is not seeing fleas inside the home off of the canine. She has not presented to the veterinary clinic. Treatments were initiated with Benadryl. May 2019*: The owner moved into a new apartment. Any other environmental exposure is unknown. Her current condition is ongoing. There are no other pets in the household. No further medical information expected.
08-Jul-2019	UAE; 19US039669; SC; U.S.A	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: 8 - 10 lbs	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-Jan-2019*	22-May-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 8 Jul 2019, the owner reported the following event for two 8-10 pound felines (all other signalments unknown). Unknown date: Started on monthly doses of FRONTLINE PLUS CATS (S40603AW) topically between the shoulder blades, by the owner. 17 May 2019: Owner applied 1 vial of FRONTLINE. 22 May 2019*: The owner started seeing fleas on the cats. 17 Jun 2019: Owner applied 1 vial of FRONTLINE. 28 Jun 2019: Owner applied 1 vial of FRONTLINE. 2 Jul 2019: Owner applied 1 vial of FRONTLINE. The owner is seeing fleas in the home. The owner is still seeing fleas on the cats. The cats are strictly indoor. No further medical information expected.
08-Jul-2019	UAE;	Species: Canine	1	1	0	Product used:	08-Jul-2019	08-Jul-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 08 Jul 2019 an animal

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 345 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).
Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.
Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00352

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	19US039673; -, U.S.A	Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown				FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company					owner reported the following event in a canine. All other signalment unknown. 04 Jul 2019: The canine was administered 1 vial of FRONTLINE PLUS 23-44 LB (lot, expiration unknown) between the shoulder blades for the first time. Two hours post administration the canine was bathed. 08 Jul 2019: The animal owner is seeing fleas. The caller was not receptive. No further information provided nor expected.
08-Jul-2019	UAE; 19US039674; CA; U.S.A	Species: Canine Breed: Shih Tzu Sex: F Sex qualifier: Neutered Age: 3.00 Year(s) Weight: 11 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-Apr-2019	02-Apr-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 8 Jul 2019, the owner reported the following event for Duchess, 3 year old, 11 pound, spayed female, Shih Tzu canine. 1 Apr 2019*: One vial of FRONTLINE PLUS DOG 5-22 LBS (S61017AL) was applied between the shoulder blades for the very first time. 2 Apr 2019*: The owner started to notice fleas and 1 tick. The tick was attached and alive. The owner removed the tick. 1 May 2019 and 1 Jun 2019: Another vial was applied. The fleas issue persisted and the owner continued to find occasional ticks (attached and alive). It is unknown if the ticks were removed. 9 Jul 2019: The issue is still ongoing. The dog has access to an open yard. There are no other pets in the household. No further medical information is expected.
08-Jul-2019	UAE; 19US039675; -, U.S.A	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: 5 - 20 lbs	3	3	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-Jul-2019	02-Jul-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 8 Jul 2019, the owner reported the following event for one 5 pound feline and two 20 pound felines (all other signalments unknown). 1 Jul 2019: First dose of FRONTLINE PLUS CATS (S41108AW) was applied topically between the shoulder blades. One of the cats had fleas for approx. 1 day prior to the application. 2 Jul 2019*: The owner continued to see a small amount of fleas on all the cats. The owner is not seeing fleas in the home. The cats are strictly indoor. No further medical information expected.
08-Jul-2019	UAE; 19US039677; -, U.S.A	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	06-Jul-2019*	07-Jul-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 8 Jul 2019, the owner reported the following event for Canine (all other signalments unknown). Unknown date: The owner noticed fleas on the dog. 6 Jul 2019: One vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) was applied between the shoulder blades. 7 Jul 2019: The flea issue persisted. 8 Jul 2019: The flea issue is still ongoing. It is unknown if the dog received the product before. The dog's environment is unknown. There are 2 other cats in the household, their status is unknown. No further medical information is expected.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 346 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00353

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
09-Jul-2019	UAE; 19US039702; -, U.S.A	Species: Canine Breed: Medium crossbred (10 - 20 Kg) Sex: F Sex qualifier: Neutered Age: 14.00 Year(s) Weight: 44 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	06-Apr-2019	09-Jun-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 9 Jul 2019 the pet owner reported the following event for an unknown 14 year old 44 pound female spayed Medium crossbred (10-20 kg). 6 Apr 2019: The owner applied 1 vial of FRONTLINE PLUS DOG 23-44 LBS to the skin between the shoulder blades for the first time and continued on a monthly basis thereafter. No fleas were seen at this time. 6 Jun 2019: Another dose was applied. *9 Jun 2019: The owner began noticing a small amount of fleas on the dog. 6 Jul 2019: The owner applied the most recent dose. 7 Jul 2019: The owner continued to notice a small amount of fleas on the dog. There are no other pets in the home. The dog has not received any baths and has normal skin. The owner is not noticing any indoor flea activity. The dog is mainly indoors but has access to a fenced in yard. No further medical information is expected.
09-Jul-2019	UAE; 19US039705; PA; U.S.A	Species: Canine Breed: Yorkshire Terrier Sex: F Sex qualifier: Neutered Age: 10.00 Year(s) Weight: 16 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	09-Jun-2019*	08-Jul-2019*	29 Day(s)	D-D	Suspected Lack of efficacy Claim: On 9 Jul 2019 the pet owner reported the following event for Lola a 10 year old 16 pound female spayed Yorkshire Terrier. *2012: The owner began applying 1 vial of FRONTLINE PLUS DOG 5-22 LBS (UNKNOWN) to the skin between the shoulder blades for the first time and continued on a monthly and year round basis thereafter. *9 Jun 2019: The most recent dose was applied. *8 Jul 2019: The dog tested positive for Lyme disease. The owner reported not seeing any ticks on the dog. There are no other pets in the home. The outdoor environment is unknown. It is unknown if the dog received any baths or has skin conditions. No further medical information expected.
03-Jul-2019	UAE; 19US039712; MI; U.S.A	Species: Feline Breed: Domestic Mediumhair (Crossbred) Sex: F Sex qualifier: - Age: 6.00 Month(s) Weight: 1.5 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: FIPRONIL 9.8% / S-METHOPRENE 11.8% / PYRIPROXYFEN 0.25% TOPICAL SOLUTION; Route: Topical / Cutaneous Was the product used ok?: Yes	01-Feb-2019*	01-Jul-2019	8 Week(s) 5 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 3 Jul 2019, the pet owner reported the following event for Church, a 6 month old, 1.5* pound, intact female, Domestic Mediumhair. 1 Feb 2019*: The owner noticed some fleas after applying FRONTLINE PLUS CATS (lot unknown). 1 Mar 2019: The patient got another dose of FRONTLINE PLUS CATS. The owner still noticed fleas. 1 Apr 2019: The patient got another dose of FRONTLINE PLUS CATS. The owner was still noticing fleas at this time. 1 May 2019: The patient got another dose of FRONTLINE PLUS CATS. The owner was still noticing fleas at this time. 1 Jun 2019: The patient switched to FRONTLINE GOLD FOR CATS (lot unknown) because the owner had heard it worked better and the cat still had some fleas. 1 Jul 2019: The patient got another dose of FRONTLINE GOLD FOR CATS. The owner was still noticing fleas at this time and is still seeing them as of 3 Jul 2019. The owner stated she is applying the FRONTLINE correctly, is not bathing the animal, and is not giving anything else at the time of giving FRONTLINE. The owner states the patient does not go outside. There are also fleas in the house and they are on the owner biting them as well. The owner stated she is spraying a growth inhibitor around the house, and has not sought further treatments for her animal other than FRONTLINE. The patient's current condition is ongoing. There is a total of 1 canine and 3 felines in the household. These

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
 Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
 *indicates Approximate date or weight

Page 347 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).
 Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.
 Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00354

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											animals each have there own case as they were also on FRONTLINE and had fleas see cases 19US039027, 19US039722, and 19US039724. No further medical information expected.
09-Jul-2019	UAE; 19US039716; OH; U.S.A	Species: Canine Breed: Beagle Sex: F Sex qualifier: Neutered Age: 8.00 Month(s) Weight: 20 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: PO-Oral Was the product used ok?: No (Route not indicated / recommended)	09-Jul-2019	09-Jul-2019	0 Day(s)	D-D	Suspected Adverse Event: On 09 Jul 2019 an animal owner reported the following event in Peanuts, a 8 month old, 20 pound, spayed female, Beagle. 09 Jul 2019: The canine licked the FRONTLINE PLUS CATS (lot 1141101AW invalid) that was applied to a feline on the evening of 08 Jul 2019. The canine began to hyper salivated, vomited 3 times, and recovered. No further information provided nor expected.
09-Jul-2019	UAE; 19US039717; -; U.S.A	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	15-Jun-2019*	09-Jul-2019	24 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 09 Jul 2019, animal owner reported the following event for a cat. All signalment is unknown. *15 Jun 2019: The pet owner applied FRONTLINE PLUS CATS (Lot unknown). 09 Jul 2019: The pet owner seeing live fleas. The pet owner could not confirm if the entire contents were applied to the cat as the cat is ferral. No further information expected.
03-Jul-2019	UAE; 19US039722; MI; U.S.A	Species: Feline Breed: Domestic Mediumhair (Crossbred) Sex: M Sex qualifier: Neutered Age: 3.00 Year(s) Weight: 6 lbs*	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: FIPRONIL 9.8% / S-METHOPREN E 11.8% / PYRIPROXYFE N 0.25% TOPICAL SOLUTION; Route: Topical / Cutaneous Was the product used ok?: Yes	01-Feb-2019*	01-Jul-2019	8 Week(s) 5 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 3 Jul 2019, the pet owner reported the following event for Einstein, a 3 year old, 6 pound, neutered male, Domestic Mediumhair. 1 Feb 2019*: The owner noticed some fleas after applying FRONTLINE PLUS CATS (lot unknown). 1 Mar 2019: The patient got another dose of FRONTLINE PLUS CATS. The owner still noticed fleas. 1 Apr 2019: The patient got another dose of FRONTLINE PLUS CATS. The owner was still noticing fleas at this time. 1 May 2019: The patient got another dose of FRONTLINE PLUS CATS. The owner was still noticing fleas at this time. 1 Jun 2019: The patient switched to FRONTLINE GOLD FOR CATS (lot unknown) because the owner had heard it worked better and the cat still had some fleas. 1 Jul 2019: The patient got another dose of FRONTLINE GOLD FOR CATS. The owner was still noticing fleas at this time and is still seeing them as of 3 Jul 2019. The owner stated she is applying the FRONTLINE correctly, is not bathing the animal, and is not giving anything else at the time of giving FRONTLINE. The owner states the patient does not go outside. There are also fleas in the house and they are on the owner biting them as well. The owner stated she is spraying a growth inhibitor around the house, and has not sought further treatments for her animal other than FRONTLINE. The patient's current condition is ongoing.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 348 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

v1.2

ED_005739D_00014390-00355

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											There is a total of 1 canine and 3 felines in the household. These animals each have there own case as they were also on FRONTLINE and had fleas see cases 19US039027, 19US039712, and 19US039724. No further medical information expected.
03-Jul-2019	UAE; 19US039724; MI; U.S.A	Species: Feline Breed: Domestic Mediumhair (Crossbred) Sex: F Sex qualifier: - Age: 2.00 Year(s) Weight: 4 lbs*	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: FIPRONIL 9.8% / S-METHOPRENE 11.8% / PYRIPROXYFEN 0.25% TOPICAL SOLUTION; Route: Topical / Cutaneous Was the product used ok?: Yes	01-Feb-2019*	01-Jul-2019	8 Week(s) 5 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 3 Jul 2019, the pet owner reported the following event for Caramel, a 2 year old, 4 pound, spayed female, Domestic Mediumhair. 1 Feb 2019*: The owner noticed some fleas after applying FRONTLINE PLUS CATS (lot unknown). 1 Mar 2019: The patient got another dose of FRONTLINE PLUS CATS. The owner still noticed fleas. 1 Apr 2019: The patient got another dose of FRONTLINE PLUS CATS. The owner was still noticing fleas at this time. 1 May 2019: The patient got another dose of FRONTLINE PLUS CATS. The owner was still noticing fleas at this time. 1 Jun 2019: The patient switched to FRONTLINE GOLD FOR CATS (lot unknown) because the owner had heard it worked better and the cat still had some fleas. 1 Jul 2019: The patient got another dose of FRONTLINE GOLD FOR CATS. The owner was still noticing fleas at this time and is still seeing them as of 3 Jul 2019. The owner stated she is applying the FRONTLINE correctly, is not bathing the animal, and is not giving anything else at the time of giving FRONTLINE. The owner states the patient does not go outside. There are also fleas in the house and they are on the owner biting them as well. The owner stated she is spraying a growth inhibitor around the house, and has not sought further treatments for her animal other than FRONTLINE. The patient's current condition is ongoing. There is a total of 1 canine and 3 felines in the household. These animals each have there own case as they were also on FRONTLINE and had fleas see cases 19US039027, 19US039712, and 19US039722. No further medical information expected.
09-Jul-2019	UAE; 19US039732; MI; U.S.A	Species: Canine Breed: Terrier (Jack Russell) Sex: M Sex qualifier: Neutered Age: 8.00 Year(s) Weight: 35.000 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: Unknown Flea Shampoo; Route: Topical / Cutaneous Was the product used ok?: Yes	01-Jul-2019	04-Jul-2019	3 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 09 Jul 2019, the pet owner reported the following event for Scooby, a 35 pound, 8 year old (31 Jan 2011), neutered male, Jack Russell Terrier. 2011*: The dog began receiving FRONTLINE PLUS DOG 23-44 LBS (S61710AL) monthly by the owner applying 1 full vial each month between the shoulder blades of the dog. 01 Jul 2019: The pet owner bathed the dog in the morning with an unknown flea shampoo and let the dog completely dry and then the owner applied the most recent dose of FRONTLINE PLUS between the shoulder blades of the dog. 04 Jul 2019: The owner found one live flea on the dog. 09 Jul 2019: The owner found one live flea on the dog. The dog is the only pet in the home. Dog only goes outside to use the bathroom. The owner has noticed no change in the outside environment. They vacuum the carpet daily and have treated the carpet with Knockout from the veterinarian. Owner also washes the dog's bedding. The owner is not getting bit. No further medical information expected. UPDATE 15 Jul 2019: The pet owner reported that she routinely applies FRONTLINE PLUS on the 1st of every month. No further medical information expected.
09-Jul-2019	UAE; 19US039743;	Species: Canine Breed: Terrier	1	1	0	Product used: FIPRONIL	01-May-2013	30-May-2019	29 Day(s)	D-D	Suspected Lack of Efficacy Claim and Suspected Adverse Event: On 09 Jul 2019 an animal owner reported the following event in

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 349 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00356

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	VA; U.S.A	(Jack Russell) Sex: M Sex qualifier: Neutered Age: 6.00 Year(s) Weight: 23.1 lbs				10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes					Willie, a 6 year old, 23.1 pound, male neutered, Jack Russell Terrier. 2013*: The canine started receiving applications of FRONTLINE PLUS 5-22 LB (lot, expiration unknown. Package unavailable) on the beginning of every month. 01 May 2019: The canine was administered 1 entire vial of FRONTLINE PLUS between the shoulder blades. 30 May 2019: The animal owner is seeing increased number of fleas in the environment and live fleas on canine. 03 Jun 2019: The canine was administered 1 chew of NEXGARD 68 MG (lot AA165518A expiration Aug 2021). (Reported in case 19US042803). 10 Jun 2019: The canine is scratching and biting. No fleas seen. 25 Jun 2019: The canine presented to the attending veterinarian for ongoing clinical signs. No fleas were seen at time of administration. The canine was prescribed Apoquel and Douxo medicated shampoo. 02 Jul 2019: Animal owner stopped the Apoquel because canine stopped scratching and itching. 05 Jul 2019: The canine began scratching and biting. No fleas seen. 08 Jul 2019: The animal owner started the canine on Apoquel again. 09 Jul 2019: Canine no longer scratching and biting. Animal owner applied FRONTLINE PLUS. There are no other animals in the household. Animal has exposure to the outdoors. No further information provided nor expected.
09-Jul-2019	UAE; 19US039750; MD; U.S.A	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: 3.00 Year(s) Weight: 7 - 10 lbs	3	3	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	08-Jul-2019	09-Jul-2019	1 Day(s)	D-D	Suspected Adverse Event: On 9 Jul 2019 the pet owner reported the following event for 3 felines with a weight range of 7 to 10 pounds, and ranging in 3 to 6 years of age with no further signalment known. 8 Jul 2019: The pet owner applied FRONTLINE PLUS CATS (541140AW) (invalid lot number), 1 vial topically, at the base of the skull for each of the three felines for the first time. 9 Jul 2019: All three felines developed alopecia, pruritus, and inflammation at the application site. The veterinarian treated all 3 felines with methylprednisolone and Benadryl at the pet owner's home. No further information is available at this time. UPDATE 09 Jul 2019: Per the pet owner both cats have received injections of Depo Medrol (Detemedor) for allergic dermatitis. No further medical information is expected.
09-Jul-2019	UAE; 19US039801; -; U.S.A	Species: Canine Breed: Canine (unknown) Sex: F Sex qualifier: Unknown Age: 14.00 Year(s) Weight: Unknown	1	1	1	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	01-Jun-2019*	02-Jun-2019*	1 Day(s)	D-A	Suspected Adverse Event: On 9 Jul 2019, the pet owner reported the following event for a 14 year old female dog of further unknown signalment. 1 Jun 2019*: The patient received a dose of FRONTLINE PLUS DOG 45-88 LBS (lot and expiration unknown). 2 Jun 2019*: The patient passed away due to many unknown issues and old age, one being hip problems. It is unknown when all the problems exactly began. Further information is unknown as the owner refused further inquiry. No further medical information expected.

N/A signifies the information for this field is either not available or not applicable

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

Report printed on 25-Oct-2019 at 8:39:59PM

*indicates Approximate date or weight

Page 350 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00357

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
10-Jul-2019	UAE; 19US039809; -, U.S.A	Species: Canine Breed: German Shepherd Dog Sex: M Sex qualifier: Neutered Age: 3.50 Year(s) Weight: 62 - 65 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	17-Jun-2017*	20-Jun-2019	3 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Jul 2019, the owner reported the following event for Verdinate, a 62-65 pound, male neutered, 3.5 year old, German Shepard Dog. 17 Jun 2019: One vial of the FRONTLINE PLUS DOG 45-88 LBS (S62204) was applied topically in between the shoulder blades by the owner. 20 June 2019: The owner noticed a large amount of fleas on the pet. The dog is indoor/outdoor. The dog has access to a fenced in yard. This is the first time the owner has noticed fleas on the pet. The owner has used FRONTLINE for years per the owner at an unknown start date on the pet. This is the only pet within the home. Owner declined additional information. No further medical information is expected.
09-Jul-2019	UAE; 19US039822; -, U.S.A	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	16-Jun-2019*	09-Jul-2019	23 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 9 Jul 2019, the pet owner reported the following event for an unknown Canine. All other signalments unknown, pet owner declined to complete report. 16 Jun 2019*: 1 vial of FRONTLINE PLUS DOG (product unsubstantiated, lot unknown). Owner declined to complete report. 9 Jul 2019: 2 fleas were seen on the dog. The dog goes out for potty breaks and recreation. It is unknown how long the dog has been on FRONTLINE. No further medical information is expected.
09-Jul-2019	UAE; 19US039848; -, U.S.A	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-Jul-2019*	09-Jul-2019*	8 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 09 Jul 2019, animal owner reported the following event for a cat. All signalment is unknown. *01 Jul 2019: The pet owner applied FRONTLINE PLUS CATS (Lot unknown) topically. *09 Jul 2019: The pet owner is still seeing fleas. The cat is indoor mostly but goes outside occasionally. All additional information as declined by the pet owner. No further information expected.
09-Jul-2019	UAE; 19US039856; OH, U.S.A	Species: Canine Breed: Shetland Sheep Dog (Sheltie) Sex: F Sex qualifier: Neutered Age: 4.00 Year(s) Weight: 30 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: Dawn; Route: Topical / Cutaneous Was the product used ok?: Yes	26-Jun-2019	09-Jul-2019*	13 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 9 Jul 2019, the pet owner reported the following event for Hope, a 30 pound*, 4 year old, female spayed Shetland Sheep Dog. 25 Jun 2019*: The owner bathed the dog in Dawn to kill fleas. 26 Jun 2019: 1 vial of FRONTLINE PLUS DOG 23-44 LBS(S60801AL) was applied to the dog in one area between the shoulder blades. 9 Jul 2019: The owner saw 5 fleas on the dog and a lot of flea dirt. The owner has been treating the dog with FRONTLINE monthly year round since 2015*. The dog goes out for potty breaks and recreation in a yard with an electric fence, no urban wildlife seen. There are no fleas in the home biting the humans. There is one other dog in the home who was treated with FRONTLINE see case 19US040482. No further information.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 351 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00358

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
09-Jul-2019	UAE; 19US039883; -; U.S.A	Species: Feline Breed: Feline (unknown) Sex: X Sex qualifier: Mixed Age: - Weight: Unknown	3	3	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	05-Jun-2019*	05-Jul-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 9 Jul 2019, a pet owner reported the following event for 3 felines of mixed sex and further unknown signalments. Apr 2019: The owner began using FRONTLINE PLUS CATS (lot unknown) topically. 5 Jul 2019: The owner applied the most recent dose to all 3 cats. The cats did have fleas on them, but not a large amount. 9 Jul 2019: The owner is still seeing fleas. All 3 cats are indoor only. No further medical information expected.
09-Jul-2019	UAE; 19US039885; IL; U.S.A	Species: Canine Breed: Spaniel (Brittany) Sex: M Sex qualifier: Neutered Age: 1.00 Year(s) Weight: 40 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-Jul-2019	09-Jul-2019	8 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 9 Jul 2019, the pet owner reported the following event for Louie, a 1 year old, 40 pound, neutered male Brittany Spaniel. 1 Jul 2019: A single dose of FRONTLINE PLUS DOG 23-44 LBS (S62308AW) was applied topically between the shoulder blades by the pet owner. 9 Jul 2019: 3 ticks were found on the dog, 1 of which was attached and dead while the remaining 2 were live and were not attached to the dog. Ticks were removed by the animal owner. Per the owner, the dog has been receiving FRONTLINE PLUS monthly since 2018*. The dog goes out approximately 2 times per day in a grassy yard. No further medical information expected.
09-Jul-2019	UAE; 19US039891; ME; U.S.A	Species: Feline Breed: Domestic Longhair (Crossbreed) Sex: M Sex qualifier: - Age: 8.00 Month(s) Weight: 3 - 5 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	02-Jul-2019	09-Jul-2019*	1 Week(s)	D-D	Suspected Adverse Event and Suspected Lack of Efficacy Claim : On 9 Jul 2019, the pet owner reported the following event for Flokey, a 8 month old, 3 to 5 pound*, intact male, Domestic Longhair. 2 Jul 2019: There were a large amount of fleas on the cat and he was scratching. The owner purchased a 3 pack of FRONTLINE PLUS CAT(R40601AW) from the hardware store and applied 1 vial to the cat in one are between the shoulder blades for the very first time. 9 Jul 2019*: The cat is ripping his hair out and scratching a lot more than he was. There are a large amount of fleas on the cat. The cat is indoor/outdoor. He was not seen by the veterinarian for this issue and the owner has not provided treatment. No further medical information. UPDATE 19 Jul 2019: After further review, lack of efficacy was added to the VeDDRA terms.
09-Jul-2019	UAE; 19US039898; OH; U.S.A	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-Jul-2019*	02-Jul-2019*	1 Day(s)	D-D	Suspected Adverse Event: On 9 Jul 2019, a pet owner reported the following event for 2 canines of unknown signalment. Unknown Date: The dogs started using FRONTLINE PLUS DOG 45-88 LBS (S62518AX) topically between the shoulders. 1 Jul 2019*: The most recent dose was applied. 2 Jul 2019*: The owner said the dogs began itching more than normal and the dogs hair started to come out from itching. 9 Jul 2019: The dogs are still itching, the owner has not taken the dogs to the vet or treated with anything. No further medical information expected.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 352 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00359

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
09-Jul-2019	UAE; 19US039909; -; U.S.A	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: F Sex qualifier: Neutered Age: 1.00 Year(s) Weight: 10 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: Vinegar Bath; Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	05-Jul-2019*	08-Jul-2019	3 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 9 Jul 2019, the owner reported the following event for Lily, a 10 pound, 1 year old*, spayed female Domestic Shorthair. 30 Jun 2019: The owner noticed that Lily increased her grooming and seemed to be biting her paws more often. 5 Jul 2019*: Lily received her first dose of FRONTLINE PLUS CATS (S41004AW) topically in an unknown location. About 2 hours, the owners gave a vinegar bath. 8 Jul 2019: The owners reported still seeing an unknown amount fleas near Lily's head. Fleas were not noticed prior to FRONTLINE administration. This was her first time receiving the product. No further information at the time. UPDATE: 22 JUL 2019: Upon internal review, added vinegar bath to product screen and removed it from treatment box.
09-Jul-2019	UAE; 19US039936; -; U.S.A	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	14-Jun-2019	15-Jun-2019	1 Day(s)	D-D	Suspected Adverse Event and Suspected Lack of Efficacy Claim : On 09 JUL 2019, Animal owner reported the following event for 2 cats. All signalment is unknown. 14 Jun 2019: The pet owner applied FRONTLINE PLUS CATS (Lot unknown) topically between the shoulder blades for the first time. The cats had pre-existing fleas. 15 Jun 2019: Both cats broke out in a rash at and around the application site from scratching. 09 Jul 2019*: The pet owner is still seeing fleas. Both cats are indoor/ outdoor cats. The cats were bathed in dawn dish soap on an unknown date. The cats have not seen a vet for evaluation and the environment has not been treated. No further information expected.
09-Jul-2019	UAE; 19US039948; CA; U.S.A	Species: Feline Breed: Domestic Longhair (Crossbreed) Sex: F Sex qualifier: Neutered Age: 3.00 Year(s) Weight: 9 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: Dawn detergent; Route: Topical / Cutaneous Was the product used ok?: Yes	01-Jul-2019	09-Jul-2019	8 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 9 Jul 2019, a pet owner reported the following event for Millie, a 3* year old, 9 pound, spayed female Domestic Longhair. 2016*: The cat began receiving monthly FRONTLINE PLUS CATS (Lot Unknown), topically between the shoulder blades, year round. 1 Jul 2019: The cat received 1 application of FRONTLINE PLUS CATS (S41004AW), topically between the shoulder blades in one spot. 8 Jul 2019: The pet owner bathed the cat in Dawn detergent, fogged the house, and washed bedding. 9 Jul 2019: The pet owner noticed 3 live fleas on the cat. There are no other pets in the house and the cat is indoor only. The cat was scratching prior to application of FRONTLINE and has continued to scratch since. The scratching did not get worse and the pet owner was not noticing fleas prior to application. No further medical information expected.
09-Jul-2019	UAE; 19US039973; CO; U.S.A	Species: Canine Breed: Retriever (Curly-Coat) Sex: F Sex qualifier: Neutered Age: 2.00 Year(s) Weight: 37 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the	26-Jun-2019	26-Jun-2019	0 Day(s)	D-D	Suspected Adverse Event: On 09 Jul 2019, the veterinary clinic staff reported via email the following event for Lulu, a 2 year old (born 13 Oct 2016), unknown weight, spayed female Curly-Coat Retriever. 27 Jun 2019*: She received FRONTLINE PLUS DOG 5-22 LBS (unsubstantiated) (lot unknown) an unknown volume via an unknown route at an unknown location of the body. She began experiencing restless behaviors, mucousy diarrhea, and vomiting bile an unknown time post application, but the same day as application. It is unknown if she presented to the veterinary clinic. It is unknown if any treatments were initiated. It is unknown if she previously received FRONTLINE PLUS. No

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 353 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00360

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						product used ok?: Unknown to Company					further medical information expected. UPDATE 12 Jul 2019: Per phone call received the following update was made: Lulu is a 37 pound, 2 year old (born 13 Oct 2016), spayed female, Curly-Coat Retriever. 26 Jun 2019: The pet owner applied FRONTLINE PLUS (unsubstantiated) (Unknown lot number), with 1 dose applied topically on an unknown site by the pet owner in the evening. Later that evening the dog began experiencing restless behaviors, mucousy diarrhea, and vomiting bile. The patient did not present to the clinic and did not receive any treatment. It is unknown if the dog recovered in full. No further medical information expected.
09-Jul-2019	UAE; 19US039974; AR; U.S.A	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: F Sex qualifier: Unknown Age: 3.00 Month(s) Weight: 3.5 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-Jun-2019*	01-Jun-2019*	0 Day(s)	D-C	Suspected Adverse Event: On 9 Jul 2019, the pet owner reported the following event for Poppy, a 3 month old, 3.5 pound, intact female, Domestic Shorthair. 1 May 2019*: The patient received her first dose of FRONTLINE PLUS CATS(S41004AW) with no reaction noted. 1 Jun 2019*: The patient received another dose of FRONLTINE PLUS CATS(S41004AW). At this time fleas were seen on the animal, see case 19US041433 for further information. An hour after the patient became non responsive and went limp. The owner washed the cat with Dawn dish soap. The patient recovered after 3 to 4 hours. No further medical information expected.
09-Jul-2019	UAE; 19US039977; NC; U.S.A	Species: Canine Breed: Welsh Corgi Sex: U Sex qualifier: Unknown Age: - Weight: 35.000 lbs*	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-Jul-2019	07-Jul-2019	6 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 9 Jul 2019, the owner reported the following event for 2 Welsh Corgis, weighing between 35-40 pounds, all other signalment unknown. 1 Jul 2019: One vial of the FRONTLINE PLUS DOG 23-44 LBS (Lot Unknown) was applied topically in between the shoulder blades by the owner. 7 Jul 2019: The owner noticed a small amount of fleas on the pet since applying the product. The dogs are indoor/outdoor. The dog has access to a fenced in yard. Foxes have been noticed in the area. A few indoor fleas have been spotted but the owner thinks these have fallen off of the pet and do not bite him or his wife. This is the first time the owner has noticed fleas on the pet after using FRONTLINE for years, year round on the dogs per owner. There are 7 cats in the home that are treated with FRONTLINE see additional case 19US040395 and 2 larger dogs that are also treated see additional case 19US040034. No further medical information is expected.
09-Jul-2019	UAE; 19US039979; DE; U.S.A	Species: Canine Breed: Retriever (Labrador, Chocolate) Sex: F Sex qualifier: Neutered Age: 4.00 Year(s) Weight: 85 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	25-Jun-2019	09-Jul-2019	2 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 9 Jul 2019, the pet owner reported the following event for Roxy, a 4 year of, 85 pound, female spayed, female spayed, Retriever. 25 Jun 2019: 1 vial of FRONTLINE PLUS DOG 45-88 LBS (S62202AX) was applied to the dog in one area between the shoulder blades. 9 Jul 2019: The owner saw 1 flea on the dog. It is unknown how often the owner treats with FRONTLINE. There is one other pet in the home, the species is unknown. The dog goes out for potty breaks and recreation in fenced in yard. There is no flea activity in the home. The dog has not had a bath recently or gone swimming. The dog does not have a history of skin issues. No further information.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 354 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00361

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
09-Jul-2019	UAE; 19US040024; TX; U.S.A	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-Jul-2019*	02-Jul-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 9 July 2019, the owner reported the following event for a canine(all other signalments unknown). 1 July 2019*: The first vial of FRONTLINE PLUS DOG 89-132 LBS (R62114AR) was applied between the shoulder blades, by the pet owner. It is unknown if fleas were seen before application. 2 July 2019*: The dog had a large amount of fleas. The dog does not get bathed. The owner is not seeing any flea activity in the home. The dog stays inside the home 90% of the time. No further medical information is expected. UPDATE 12 July 2019: Checked FDA box. No further information expected.
09-Jul-2019	UAE; 19US040034; NC; U.S.A	Species: Canine Breed: German Shepherd Dog Sex: U Sex qualifier: Unknown Age: 10.00 Month(s) Weight: 63 - 65 lbs	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-Jul-2019	07-Jul-2019	6 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 9 Jul 2019, the owner reported the following event for 2 German Shepards, weighing between 63-65 pounds, 10 months of age*, all other signalment unknown. 1 Jul 2019: One vial of the FRONTLINE PLUS DOG 45-88 LBS (Lot Unknown) was applied topically in between the shoulder blades by the owner. 7 Jul 2019: The owner noticed a small amount of fleas on the pet since applying the product. The dogs are indoor/outdoor. The dog has access to a fenced in yard. Foxes have been noticed in the area. A few indoor fleas have been spotted but the owner thinks these have fallen off of the pet and do not bite him or his wife. This is the first time the owner has noticed fleas on the pet after using FRONTLINE for years, year round on the dogs per owner. There are 7 cats in the home that are treated with FRONTLINE see additional case 19US040395 and 2 smaller dogs that are also treated see additional case 19US039977. No further medical information is expected.
09-Jul-2019	UAE; 19US040037; OK; U.S.A	Species: Canine Breed: Shetland Sheep Dog (Sheltie) Sex: M Sex qualifier: - Age: 15.00 Year(s) Weight: 27 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: Unknown pet shampoo.; Route: Topical / Cutaneous Was the product used ok?: Yes	22-Jun-2019*	23-Jun-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 9 Jul 2019, the pet owner reported the following event for Toby , a 27 pound, 15 year old, intact male, Shetland Sheep Dog. 9 Jun 2019*: The owner bathed the dog in an unknown pet shampoo. 22 Jun 2019*: There were no fleas on the dog. 1 vial of FRONTLINE PLUS DOG 23-44 LBS was applied to the dog in one area between the shoulder blades. The owner has been seeing 10+ fleas on the dog daily since the application. The dog has been receiving FRONTLINE PLUS since Jan. 2019 on the first of the month. The dog goes out for potty breaks and recreation on 1 acre of land. Is is unknown if there is flea activity in the home. It is unknown if there are other pets in the home. The dog has no history of skin issues. No further information is expected.
09-Jul-2019	UAE; 19US040048; OH; U.S.A	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: 66.000 - 68.000 lbs	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical /	22-May-2019	29-May-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 9 Jul 2019, the owner reported the following event for 2 canines (all other signalments unknown). 22 May 2019: One vial of FRONTLINE PLUS DOG 45-88 LBS (S62202AX) was applied between the shoulder blades for the very first time. 29 May 2019: The owner started to notice fleas on the pets for the first time. No fleas were noted in the household. 22 Jun 2019: Another vial was applied.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 355 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00362

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Cutaneous Was the product used ok?: Yes					10 Jul 2019: The fleas issue is still ongoing. The dogs have access to a fenced in yard. No further medical information is expected.
09-Jul-2019	UAE; 19US040049; PA; U.S.A	Species: Feline Breed: Domestic Longhair (Crossbreed) Sex: M Sex qualifier: Neutered Age: 2.00 Year(s) Weight: 7 lbs	3	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	09-Jul-2019	09-Jul-2019	0 Day(s)	D-D	Suspected Adverse Event: On 9 Jul 2019, the owner reported the following event for Willie, 2 year old, 7 pound, neutered male, Domestic Longhair feline. 9 Jul 2019: One vial of FRONTLINE PLUS CATS (S41004AW) was applied between the shoulder blades. After 2 hours the cat experienced sneezing. The pet did not present to the clinic and no treatment was provided. there are 2 other cats in the household that also received the product nd experienced no issue. No further medical information is expected.
09-Jul-2019	UAE; 19US040053; -; U.S.A	Species: Canine Breed: Terrier (Jack Russell) Sex: M Sex qualifier: Neutered Age: 7.00 Year(s) Weight: 15 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: Advantage Shampoo; Route: Topical / Cutaneous Was the product used ok?: Yes	03-May-2019	04-May-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 9 Jul 2019, the pet owner reported the following event for Quincy a 15 pound, 7-8 year old*, male neutered Terrier mix. 3 May 2019: He was not having an issue with fleas. 1 vial of FRONTLINE PLUS DOG 5-22 LBS (S60714AX) was applied to the dog for the first time in one area between the shoulder blades. The owner has been seeing a moderate to large amount of fleas on the dog daily since the application. 3 Jun 2019: The owner bathed the dog in Advantage shampoo and applied 1 vial of FRONTLINE. The owner has been seeing a moderate to large amount of fleas on the dog since the application. The dog has never had an issue with fleas, and has never had a flea topical applied. The dog goes out for potty breaks and recreation in fenced in yard where there is a chicken coup. The chickens are treated for fleas. There are two cats in the home treated with a different flea product and are not having an issue with fleas. There are fleas in the home biting the humans. The house and the yard have been treated two times since the FRONTLINE was applied. No further information.
01-Jul-2019	UAE; 19US040058; -; U.S.A	Species: Feline Breed: Domestic Mediumhair (Crossbred) Sex: F Sex qualifier: Neutered Age: - Weight: 9 lbs	2	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	17-Jun-2019	17-Jun-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 1 Jul 2019, the pet owner reported the following event for a feline a 9 pound, female spayed Domestic mediumhair. 17 Jun 2019: 1 vial of FRONTLINE PLUS CATS (S40815AW) was applied to the cat in one area between the shoulder blades. The owner has been seeing 5-10 fleas on the cats daily since the application. The owner treats seasonally 8 months out of the year, First application Jun 2019. The cats in indoor only and no history of skin issues and has not had a bath recently. There is 1 dog in the home treated with FRONTLINE and not having an issue with fleas. There is one cat in the home treated with Advantage , and 1 cat outdoors not treated. There is one other cat in the home treated with FRONTLINE having an issue with fleas, see case 19US038392. No further medical information.
08-Jul-2019	UAE; 19US040059; MI; U.S.A	Species: Feline Breed: Feline (unknown) Sex: M	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE	04-Mar-2019*	05-Mar-2019*	N/A	D-C	Suspected Adverse Event & Suspected Lack of Efficacy Claim: On 8 Jul 2019, the pet owner reported the following events for Smudge, a one year old, 10 pound*, neutered male, feline of further unknown signalment.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 356 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00363

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: Neutered Age: 1.00 Year(s) Weight: 10 lbs				12% SPOT ON Other products used: unknown manufacturer's flea control product; Dawn dish detergent; unknown flea shampoo; Route: Topical / Cutaneous Was the product used ok?: Yes					Unknown dates: Over the winter, the pet owner and her partner began finding an unknown number of fleas on Smudge, on themselves, and throughout their home. An unknown time after noticing fleas on the feline, the reporter began bathing him with Dawn dish detergent, pro re nata (PRN), on unknown dates via unknown frequency over the next 2 to 3 months. She also treated the home for the same duration. Feb 2019*: An unknown brand/manufacturer's flea control product was administered. The volume, route, and location of administration is unknown; however, the reporter continued to find fleas on Smudge, on her person, and throughout the home for the 30 days following product application. Mar 2019 (unknown dates): Two vials of FRONTLINE PLUS CATS (FL+) (S40717AW) were purchased by the reporter's partner from a local retailer. Of the vials purchased, one was then applied topically between the shoulder blades for the first time. An unknown duration after product application, on unknown dates, Smudge's health began to decline. He was experiencing weight loss and generally didn't "look good". The reporter was unable to provide further clarification on Smudge's health or symptoms experienced. Additionally, an unknown duration following FL+ application on unknown dates, the pet owner bathed Smudge with an unknown flea shampoo no more than once weekly because she continued to find an unknown number of fleas on him. 4 Apr 2019: Six vials of FL+ were purchased from the same local retailer. One vial of FL+ was applied in the fashion as previously described and has since been applied monthly on the following dates: 4 May 2019, and 4 Jun 2019. Since applying FL+ over the course of four months, Smudge's health as continued to decline and the reporter has continued to find
10-Jul-2019	UAE; 19US040061; PA; U.S.A	Species: Canine Breed: Retriever (Golden) Sex: M Sex qualifier: Neutered Age: 9.00 Year(s) Weight: 90.0 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Low dose)	21-Jun-2019	22-Jun-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Jul 2019, the animal owner reported the following event for Bo, a 9 year old*, 90.0 pound*, neutered male Golden Retriever. 21 Jun 2019: He began receiving FRONTLINE PLUS DOG 45-88 LBS (S61101AR) one dose applied topically between the shoulders for the first time. 22 Jun 2019: The owner noticed a small amount of fleas the canine. The dog does frequent grass covered yard. He has not presented to the veterinary clinic. No diagnostics have been performed. Treatment has been initiated with an unknown topical flea spray. 30 Jun 2019: The owner bathe the canine with water only. 01 Jul 2019: The most recent date of application. The owner is still seeing a small amount of fleas on the canine and within the household. His current condition is ongoing. There are two felines in the household receiving Advantage II. The owner was seeing fleas on the canine and within the household prior to application. No further medical information expected.
08-Jul-2019	UAE; 19US040065; -; U.S.A	Species: Canine Breed: Maltese Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other	28-Jun-2019	08-Jul-2019	10 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 8 Jul 2019, the pet owner reported the following event for a less than 16 pound, male, Maltese of further unknown signalment. 28 Jun 2019: The canine received one vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) applied topically starting between the shoulder blades and stopping mid-back, for the first time. 1 Jul 2019: A foster dog was introduced into the home at which time, no fleas were seen on him/her. Before being introduced into

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 357 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00364

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)					the reporter's home, the foster dog was treated with an unknown flea control product given said canine had been covered in fleas when rescued. 7 Jul 2019: The foster dog was adopted and has since left the reporter's home. 8 Jul 2019: Following onset of incessant pruritus, the reporter then observed approximately two living fleas and approximately two deceased fleas on her Maltese. Presently, she is not finding fleas in her home, but has since washed all of her bedding. She also continues to find a couple of fleas on her Maltese. There are two other dogs in the home who are also receiving FRONTLINE PLUS and are experiencing the same problems. Please see cases 19US039421 and 19US040066. All three resident dogs go outside in the yard to go to the bathroom. The reporter described the yard as a wooded area, but then said it was not really a wooded area. No further clarification could be obtained other than the dogs also have access to an area with wood chips, a row of trees that divide her yard from her neighbor's yard, and spend time at the dock. No further medical information expected.
08-Jul-2019	UAE; 19US040066; -; U.S.A	Species: Canine Breed: Terrier Breeds (500 Series) Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	28-Jun-2019	08-Jul-2019	10 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 8 Jul 2019, the pet owner reported the following event for a less than 16 pound, male, Terrier mix of further unknown signalment. 28 Jun 2019: The canine received one vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) applied topically starting between the shoulder blades and stopping mid-back, for the first time. It cannot be confirmed if fleas were seen prior to product application. 1 Jul 2019: A foster dog was introduced into the home at which time, no fleas were seen on him/her. Before being introduced into the reporter's home, the foster dog was treated with an unknown flea control product given said canine had been covered in fleas when rescued. 7 Jul 2019: The foster dog was adopted and has since left the reporter's home. 8 Jul 2019: Following onset of incessant pruritus, the reporter then observed approximately two living fleas and approximately two deceased fleas on her Terrier mix. Presently, she is not finding fleas in her home, but has since washed all of her bedding. She also continues to find a couple of fleas on her Terrier mix. There are two other dogs in the home who are also receiving FRONTLINE PLUS and are experiencing the same problems. Please see cases 19US039421 and 19US040065. All three resident dogs go outside in the yard to go to the bathroom. The reporter described the yard as a wooded area, but then said it was not really a wooded area. No further clarification could be obtained other than the dogs also have access to an area with wood chips, a row of trees that divide her yard from her neighbor's yard, and spend time at the dock. No further medical information expected.
10-Jul-2019	UAE; 19US040068; -; U.S.A	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: -	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other	17-Jun-2019	09-Jul-2019	22 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Jul 2019, the owner reported the following event for an 85 pound canine (all other signalments unknown). 17 Jun 2019: Started on 1 vial of FRONTLINE PLUS DOG 89-132 LBS (R61814AR) topically between the shoulder blades. The dog did not have fleas prior to the application. 9 Jul 2019: The owner started seeing a moderate amount of fleas on the dog.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 358 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

v1.2

ED_005739D_00014390-00365

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: 85 lbs				products Route: Topical / Cutaneous Was the product used ok?: Yes					The owner is not seeing fleas in the home. The dog goes outside for potty breaks in a fenced in yard. There was 2 other dogs treated with FRONTLINE (see case 19US040069). No further medical information expected.
10-Jul-2019	UAE; 19US040069; -, U.S.A	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: 20 lbs	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	17-Jun-2019	09-Jul-2019	22 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Jul 2019, the owner reported the following event for two 20 pound canines (all other signalments unknown). 17 Jun 2019: Started on 1 vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) topically between the shoulder blades. The dogs did not have fleas prior to the application. 9 Jul 2019: The owner started seeing a moderate amount of fleas on the dogs. The owner is not seeing fleas in the home. The dogs go outside for potty breaks in a fenced in yard. There was another dog treated with FRONTLINE (see case 19US040068). No further medical information expected.
10-Jul-2019	UAE; 19US040076; -, U.S.A	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: 52 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	01-Jul-2019	10-Jul-2019	9 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Jul 2019 an animal owner reported the following event in a 52 pound canine. All other signalment unknown. 01 Jul 2019: A canine was applied FRONTLINE PLUS DOG 45-88 LBS (lot, expiration unknown. Caller declined). It is unknown how product was applied, if fleas were seen at time of administration, nor if this was the first dose. 10 Jul 2019: The animal owner reports still seeing fleas. The caller was not receptive. No further information provided nor expected.
10-Jul-2019	UAE; 19US040077; GA; U.S.A	Species: Canine Breed: Small crossbred (<10 Kg) Sex: M Sex qualifier: Neutered Age: - Weight: 10 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	07-Jul-2019	10-Jul-2019	3 Day(s)	D-D	Suspected Adverse Event: 10 Jul 2019: An owners mother reported the following event in an unknown canine; unknown age, 10 pound, neutered, male, small crossbreed. 07 Jul 2019: The owner administered one FRONTLINE PLUS DOGS 5-22 LBS (lot unknown, package unavailable) topically between the shoulders for the first time. 10 Jul 2019: The dog exhibited scratching and red skin. No further medical information available.
10-Jul-2019	UAE; 19US040081; GA; U.S.A	Species: Canine Breed: Canine (unknown) Sex: M Sex qualifier: Unknown Age: - Weight: 132 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical /	07-Jul-2019	10-Jul-2019	3 Day(s)	D-D	Suspected Lack of Efficacy: 10 Jul 2019: An owner reported the following event in an unknown canine; unknown age, 132 pound, unknown repro status, male, unknown breed, indoor-outdoor dog. 07 Jul 2019: The owner administered one FRONTLINE PLUS DOGS 89-132 LBS (lot unknown, package unavailable) topically between the shoulders for the first time. It is unknown if fleas were seen at the time of application. 10 Jul 2019: The dog had 1-2 fleas on the base of his tail. No further medical information available.

N/A signifies the information for this field is either not available or not applicable

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

Report printed on 25-Oct-2019 at 8:39:59PM

*indicates Approximate date or weight

Page 359 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00366

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Cutaneous Was the product used ok?: Yes					
10-Jul-2019	UAE; 19US040127; TX; U.S.A	Species: Canine Breed: Yorkshire Terrier Sex: M Sex qualifier: - Age: 8.00 Year(s) Weight: 14 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	19-May-2019	31-May-2019*	N/A	D-D	Suspected Adverse Event: On 10 Jul 2019, the pet owner reported the following event for Ace, a 8 year old*, 14 pound, intact male, Yorkshire terrier. 1 May 2019*: The owner stated her dog was itching. 19 May 2019: The patient began receiving FRONTLINE PLUS DOG 5-22 LBS (\$61902AL). 20 May 2019*: The itching seemed to stop. 31 May 2019*: The itching returned, but no fleas were seen. 19 Jun 2019: The patient got another dose of FRONTLINE PLUS. A hotspot was noticed on the animal's back sometime after this dose of FRONTLINE, exact timeframe is unknown. The owner gave the dog an Oatmeal Shampoo bath, Benadryl, and sprayed the dog with vinegar. The patient's current condition is ongoing. No further medical information expected.
10-Jul-2019	UAE; 19US040130; TX; U.S.A	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: 75 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	07-Jul-2019	08-Jul-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Jul 2019 the pet owner reported the following event for a 75 pound canine of unknown further signalment. Unknown Date: Started on FRONTLINE PLUS DOG 45-88 LBS (lot and expiration unknown), 1 dose topically to an unknown application site. 7 Jul 2019: The most recent dose was applied. The pet owner reported that there was an infestation inside the home at the time of application. 8 Jul 2019*: The pet owner stated she was still seeing fleas on the canine and decided to treat with Hartz UltraGuard Plus Flea & Tick Shampoo, Sergeant's Gold Flea & Tick Cat Shampoo, and an unknown natural flea repellent containing peppermint. 10 Jul 2019: The pet owner reported that she is no longer seeing fleas on her dog. It is unknown if there are fleas currently inside the home. It is unknown where the canine spends the majority of the time and what outside areas they have access to. There are no other pets in the home. No further medical information is expected.
10-Jul-2019	UAE; 19US040132; -, U.S.A	Species: Canine Breed: Australian Cattle Dog Sex: F Sex qualifier: Unknown Age: - Weight: 27 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	17-Jun-2019	09-Jul-2019	22 Day(s)	D-D	Suspected Lack of Efficacy Claim: 10 Jul 2019: An owner reported the following event in an unknown dog; unknown age and repro status, 27 pound, female, Australian Cattle Dog mix, indoor-outdoor. 17 May 2019: The owner administered one dose of FRONTLINE PLUS DOGS 23-44 LBS (lot unknown, package unavailable) topically between the shoulders for the first time. There were no fleas seen at the time of application. 17 Jun 2019: The owner administered one dose topically between the shoulders. There were no fleas seen at the time of application. 09 Jul 2019: The owner saw a few live and dead fleas. The owner treated with Advantage flea shampoo. There are no other animals in the home. No further medical information available.
10-Jul-2019	UAE; 19US040151; -, U.S.A	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier:	7	7	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON	01-Apr-2019*	10-Jul-2019	9 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Jul 2019, the owner reported the following event for 7 canines of unknown signalment. Mar 2019*: The owner noticed a heavy flea infestation on the pets as well as in the home. The owner applied 1 dose of FRONTLINE PLUS (product

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 360 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00367

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Unknown Age: - Weight: Unknown				Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)					unsubstantiated)(lot unknown) per pet, topically on the neck area on the following dates: 1 Apr 2019*, 1 May 2019*, 1 Jun 2019*, and 1 Jul 2019*. 2 Apr 2019*-10 Jul 2019*: The owner has seen a large amount of flea still on the pets and in the home. Per the owner, the fleas have not gotten worse, but the situation is not improving. There are 3 other cats in the home that are also on FRONTLINE PLUS (product unsubstantiated)(lot unknown) that also infested in fleas (See Case 19US040152). The owners stated that they have treated the home themselves with Adams spray and an unknown flea powder on the floor and carpets. They also intermittently use Dawn dish soap bath for relief of fleas. No further information at this time.
10-Jul-2019	UAE; 19US040152; -; U.S.A	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	3	3	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-Apr-2019*	02-Apr-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 10 Jul 2019, the owner reported the following event for 3 felines of unknown signalment. Mar 2019*: The owner noticed a heavy flea infestation on the pets as well as in the home. The owner applied 1 dose of FRONTLINE PLUS CATS (lot unknown) per pet, topically on the neck area on the following dates: 1 Apr 2019*, 1 May 2019*, 1 Jun 2019*, and 1 Jul 2019*. 2 Apr 2019*-10 Jul 2019*: The owner has seen a large amount of flea still on the pets and in the home. Per the owner, the fleas have not gotten worse, but the situation is not improving. There are 7 other indoor/outdoor dogs in the home that are also on FRONTLINE PLUS (product unsubstantiated)(lot unknown) that also infested in fleas (See Case 19US040151). The owners stated that they have treated the home themselves with Adams spray and an unknown flea powder on the floor and carpets. No further information at this time.
10-Jul-2019	UAE; 19US040165; OH; U.S.A	Species: Canine Breed: Retriever (Labrador, Black) Sex: M Sex qualifier: Neutered Age: 15.00 Year(s) Weight: 110 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	06-Jul-2019	07-Jul-2019	1 Day(s)	D-D	Suspected Adverse Event: On 10 Jul 2019, the owner reported the following event for Meaty, 15 year old, 110 pound, neutered male, Black Labrador Retriever canine. 6 Jul 2019: One vial of FRONTLINE PLUS DOG 89-132 LBS (P61704AR) was applied between the shoulder blades for the first time. 7 Jul 2019: The dog experienced vomiting. 8 Jul 2019: The dog recovered. There is one other dog in the household that also received the product and experienced symptoms (see case 19US040166). No further medical information is expected.
10-Jul-2019	UAE; 19US040166; OH; U.S.A	Species: Canine Breed: Rottweiler Sex: M Sex qualifier: Neutered Age: 13.00 Year(s) Weight: 125 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	06-Jul-2019	08-Jul-2019	2 Day(s)	D-C	Suspected Adverse Event: On 10 Jul 2019, the owner reported the following event for Kudjoe, 13 year old, 125 pound, neutered male, Rottweiler canine. 6 Jul 2019: One vial of FRONTLINE PLUS DOG 89-132 LBS (P61704AR) was applied between the shoulder blades for the first time. 8 Jul 2019: The dog experienced lethargy and pain walking. 9 Jul 2019: The dog presented to the clinic. The attending veterinarian treated with Depo and Dexamethasone injections. 10 Jul 2019: The dog recovered. There is one other dog in the household that also received the product and experienced symptoms (see case 19US040165). No further medical information is expected.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 361 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

v1.2

ED_005739D_00014390-00368

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
10-Jul-2019	UAE; 19US040182; WA; U.S.A	Species: Canine Breed: German Shepherd Dog Sex: F Sex qualifier: Neutered Age: 3.00 Year(s) Weight: 74 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	19-Jun-2019	20-Jun-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 10 Jul 2019, the owner reported the following event for Bella, 3 year, 74 pound, spayed female, German Shepherd Canine. 19 May 2019: The owner noticed the pet itching and suspected fleas. 19 Jun 2019*: One vial of FRONTLINE PLUS DOG 45-88 LBS (R62001AR) was applied between the shoulder blades for the first time this year. 20 Jun 2019: The dog continued itching. The owner suspected the fleas were still present. no fleas were noted in the household. 9 Jul 2019: Another vial was applied. 10 Jul 2019: The issue is still ongoing. The dog has access to a fenced in yard. The dog receives the product seasonally starting on unknown date. There are no other pets in the household.No further medical information is expected.
10-Jul-2019	UAE; 19US040188; NJ; U.S.A	Species: Canine Breed: Pekingese Sex: U Sex qualifier: Unknown Age: - Weight: 21 lbs	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	10-Jul-2019	10-Jul-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Jul 2019, the pet owner reported the following event for two 21 pound* Pekingese with otherwise unknown signalment. 12 May 2019: The dogs began receiving FRONTLINE PLUS 5-22 LBS (S63009BL) monthly with a 6 pack purchased at PetSmart on an unknown date. The product is applied directly on the skin between the shoulder blades. It is unknown if the dogs had fleas prior to product application, the pet owner said the dogs were not itching prior. 15 Jun 2019: The monthly dose was applied. It is unknown if the dogs had fleas prior to product application. 20 Jul 2019*: The dogs began scratching. 6 Jul 2019: The dogs were bathed with Top Paw Itch-ease dog shampoo with hydrocortisone. 10 Jul 2019: The most recent date of product application. The owner noticed fleas. The dogs do have access to a fenced yard that has trees and bushes. There is also a deck that wraps around the house, but the crawlspace underneath is blocked off by latticework. Their current condition is ongoing. The dogs have not presented to the veterinary clinic. There a total of 2 canines and 1 primarily outdoor feline in the household. The client is concerned they have a bad batch of product. No further medical information expected.
10-Jul-2019	UAE; 19US040202; MI; U.S.A	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: 7 lbs	6	6	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-Jul-2019	02-Jul-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 July 2019, the owner reported the following event for 6, 7 pounds, felines (all other signalments unknown). 1 July 2019: The first vial of FRONTLINE PLUS CATS (lot unknown) was applied between the shoulder blades, by the pet owner. 2 July 2019*: The cats had fleas. It is unknown if fleas were seen on the cats before application of the product. The cats are indoor/outdoor cats. The owner bombed the home with an unknown treatment on an unknown date. The cats were bathed in an unknown flea shampoo on an unknown date. The owner is seeing flea activity in the home. No further medical information is expected.
10-Jul-2019	UAE; 19US040214; NY; U.S.A	Species: Canine Breed: Maltese Sex: F Sex qualifier: Neutered	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON	09-Jul-2019	10-Jul-2019	1 Day(s)	D-D	Suspected Adverse Event: On 10 Jul 2019 the pet owner reported the following event for Daisy a 7 year old, 23.5 pounds, spayed female Maltese and poodle (Toy) mix. *2016: The owner began applying 1 vial of FRONTLINE PLUS DOG 23-44 LBS (M62305BL) to the skin between the shoulder

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 362 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00369

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: 7.00 Year(s) Weight: 23.5 lbs				Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes					blades for the first time and repeated on a monthly and year round basis with no issues. 9 Jun 2019: The owner applied another dose. 10 Jun 2019: The owner noticed the application site developed an amber color at the place where the product was applied; both skin and fur where the product came into contact. 11 Jun 2019: The dog went to the groomer and was bathed. The discoloration disappeared. 9 Jul 2019: The owner applied another dose. 10 Jul 2019: The owner noticed an amber coloration at the application site; both skin and fur where the product came into contact. There are no other pets in the home. The dog gets groomed regularly once per month. No further medical information expected.
10-Jul-2019	UAE; 19US040219; NC; U.S.A	Species: Feline Breed: Maine Coon Cat Sex: M Sex qualifier: Neutered Age: 1.00 Year(s) Weight: 8.0 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	30-Jun-2019	02-Jul-2019	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Jul 2019, the animal owner reported the following event for Magnus, a 1 year old*, 8.0 pound*, neutered male Maine Coon Cat. 30 Jun 2019: He began receiving FRONTLINE PLUS CATS (S41004AW) one dose applied topically between the shoulders for the first time. 02 Jul 2019: The owner noticed a small amount of fleas the feline. The feline is indoor only. He has not presented to the veterinary clinic. No diagnostics have been performed. Treatment has been initiated with Capstar. His current condition is ongoing. The owner does not bathe the feline. There are no other pets in the household. The owner was seeing fleas on the feline, but not within the household prior to application. No further medical information expected.
10-Jul-2019	UAE; 19US040274; CA; U.S.A	Species: Canine Breed: Pit Bull Sex: M Sex qualifier: - Age: 2.00 Year(s) Weight: 50 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	19-Jun-2019*	26-Jun-2019*	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: 10 Jul 2019: An owner reported the following event in Pops; a 2 year old, 50 pound, intact, male, Pit bull, outdoor only dog. 19 May 2019*: The owner administered one FRONTLINE PLUS DOGS 45-88 LBS (lot unknown, package unavailable) (product unsubstantiated, owner stated a 2 pack was purchased and was unsure what weight range) topically in an unknown location for the first time. The owner saw an unknown amount of ticks at the time of application. 19 Jun 2019*: The owner administered one tube topically in an unknown area. 26 Jun 2019*: The dog had 200 engorged ticks. The owner removed the ticks. The yard is treated by Terminex every two weeks. The owner has an unknown amount of indoor dogs not treated. No further medical information expected
10-Jul-2019	UAE; 19US040292; -; U.S.A	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-Jul-2019	10-Jul-2019	9 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Jul 2019, the pet owner reported the following event for 2 canines of unknown signalment. Unknown date: Both dogs began receiving year round, monthly doses of FRONTLINE PLUS (product unsubstantiated) (lot and expiration unknown) with the most recent dose applied on 1 Jul 2019. 10 Jul 2019: The owner noted less than 10 live fleas on each dog. There are 3 cats in the home who receive year-round monthly treatments of FRONTLINE PLUS and who do not seem to be experiencing an issue with fleas. Per the owner, both dogs spend time indoors and outdoors. Neither dog was bathed within 24 hours of receiving FRONTLINE PLUS. Further details regarding the environment are unknown. No further medical information

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 363 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00370

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											expected.
10-Jul-2019	UAE; 19US040297; -; U.S.A	Species: Canine Breed: Yorkshire Terrier Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	09-Jul-2019	10-Jul-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: 10 Jul 2019: An owner reported the following event in a Yorkshire Terrier of unknown signalment. 09 Jul 2019: The owner administered one dose FRONTLINE PLUS DOGS 5-22 LBS (lot unknown, package unavailable) topically between the shoulders for the first time. It is unknown if fleas were seen at the time of application. 10 Jul 2019: The owner is seeing an unknown amount of fleas. It is unknown if there are other animals in the home. It is unknown if this is a seasonal or year round application. It is unknown if the animal is indoor-outdoor. Owner declined to report. No further medical information available.
10-Jul-2019	UAE; 19US040340; -; U.S.A	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Overdose)	06-May-2019	01-Jun-2019	26 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Jul 2019, animal owner reported the following event for 2 domestic shorthaired cats. All signalment unknown. Apr 2018: Started monthly FRONTLINE PLUS CATS (Lot unknown) with the most recent purchase of 6 doses in Apr 2019. 06 May 2019: A dose was applied. 01Jun 2019: The pet owner noticed live fleas on her two cats. She bombed the house and bathed the cats in dawn dishsoap. 17 Jun 2019: The house was bombed again for fleas. 03 Jun 2019: A dose was applied and the pet owner was still seeing fleas. 01 Jul 2019: A dose was applied. 08 Jul 2019: The pet owner bathed the cats in dawn dishsoap. 10 Jul 2019: The pet owner is still seeing fleas. The cats are indoor/ outdoor cats and spend most of thier time in the screen in sunroom that is off the house. The pet owner apply's the product every 28 days. The pet owner has not treated the yard or outdoor environment for fleas. No further information expected.
10-Jul-2019	UAE; 19US040350; PA; U.S.A	Species: Canine Breed: Terrier Breeds (500 Series) Sex: F Sex qualifier: Neutered Age: 7.00 Year(s) Weight: 25 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: FIPRONIL SPRAY; AFOXOLANER 68 MG CHEWABLE TABLETS; Bravecto; Route: Topical / Cutaneous Was the product used ok?: Yes	06-Jul-2019	21-Apr-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 10 Jul 2019, the pet owner reported the following event for Evie, a 7 year old*, 25 pound, spayed female Terrier mix. Late 2018* through early 2019*: The dog was receiving Bravecto. The pet owner was still seeing fleas. 20 Apr 2019*: The dog began receiving NEXGARD (unsubstantiated) (lot and expiration unknown), with 3 doses purchased on an unknown date. The pet owner was still seeing fleas. 20 May 2019*: The monthly dose of NEXGARD was given. The pet owner was still seeing fleas. 20 Jun 2019: The monthly dose of NEXGARD was given. The pet owner was still seeing fleas. 19 Jun 2019*: The dog began receiving FRONTLINE SPRAY (S00510A). The bottle was purchased from Amazon on an unknown date. The dog was sprayed several times until damp, but the pet owner did not count the number of sprays. The product was then rubbed in with a gloved hand. The pet owner was still seeing fleas. 3 Jul 2019*: The dog was bathed with Dawn dish detergent. The dog was again treated with FRONTLINE SPRAY. The dog was sprayed several times until damp, but the pet owner did not count the number of sprays. The product was then rubbed in with a

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 364 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

v1.2

ED_005739D_00014390-00371

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											gloved hand. The pet owner was still seeing fleas 6 Jul 2019: The dog received FRONTLINE PLUS DOG 23-44 LBS (S61727AL) for the first time. A 3 pack was purchased from Amazon on an unknown date. The product is applied directly on the skin between the shoulder blades. Fleas were seen prior to product application. 10 Jul 2019: The owner is still noticing a mild amount of fleas. The dog does have access to a large open yard that backs up against the woods. The pet owner mentioned that a variety of wildlife travels through the yard. The dog has not presented to the veterinary clinic. The dog's current condition is ongoing. There a total of 1 canine only in the household. There are fleas on the dog, but none have been noticed in the home or on the owners. No further medical information expected.
03-Jul-2019	UAE; 19US040375; CA; U.S.A	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: 66.2 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	05-May-2019	19-May-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 3 Jul 2019, the owner reported the following event for a 66.2 pound canine (all other signalments unknown). 5 May 2019: A 6 pack of FRONTLINE PLUS DOG 45-88 LBS (S61306AR) was purchased. One vial was applied between the shoulder blades for the very first time. 19 May 2019: The owner found fleas on the dog. 5 Jun 2019: Another vial was applied. The owner started to note fleas in the household. 3 Jul 2019: The issue is still ongoing. The dog has access to a fenced in yard. There is 1 dog and 1 cat in the household also experiencing an issue with fleas (see case 19US039065, and 19US040392). No further medical information is expected.
10-Jul-2019	UAE; 19US040384; -; U.S.A	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	1	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: IVERMECTIN/P YRANTEL PAMOATE CHEWABLE 136MCG/326MG ; Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	01-Dec-2017*	01-Jan-2018*	31 Day(s)	D-A	Suspected Adverse Event: 10 Jul 2019: An owner reported the following event in a canine of unknown signalment. 01 Dec 2017*: The owner administered one dose FRONTLINE PLUS DOGS 45-88 LBS (lot unknown, package unavailable) and HEARTGARD PLUS (136 MCG/114 MG)(lot/expiration date unknown, package unavailable) (*products weight range unsubstantiated) in unknown manners. 01 Jan 2018*: The dog died. It is unknown if this was a euthanasia or natural cause. The owner reported in passing while requesting information on expiration dates for the product. Dates approximate for reporting purposes only. No further medical information expected or available.
10-Jul-2019	UAE; 19US040385; PA; U.S.A	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: F Sex qualifier: Neutered	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other	20-Jun-2019	06-Jul-2019	16 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 July 2019, the owner reported the following event for Chicken nugget, 8 years old*, 9 pounds*, spayed female, Domestic Shorthair(crossbreed). 20 June 2019*: The first vial of FRONTLINE PLUS CATS(S41004AW) was applied between the shoulder blades, by the pet owner. 6 July 2019: The cat had an unknown amount of dog ticks and

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 365 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00372

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: 8.00 Year(s) Weight: 9 lbs				products Route: Topical / Cutaneous Was the product used ok?: Yes					deer ticks. The cat does not get bathed. The owner is not seeing any tick activity in the home. The cat is an indoor/outdoor cat. There are 3 other cats in the home that are not having any issues with ticks but are on another product. No further medical information is expected.
10-Jul-2019	UAE; 19US040389; CA; U.S.A	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: 23 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	20-Mar-2008	21-Mar-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 10 Jul 2019, the owner reported the following event for a canine weighing 23 pound (all other signalments unknown). 20 Mar 2019: One vial of FRONTLINE PLUS DOG 23-44 LBS (P61525AL) was applied between the shoulder blades. 21 Mar 2019: The found 6 fleas on the pet. 20 Apr 2019 and 20 May 2019: Another vial was applied. No fleas were noted in the household. 10 Jul 2019: The owner has continued to find fleas daily. The dog has access to an open yard. The dog has received the product since 2008* with no issue. There is one other dog in the household also experiencing an issue with fleas (see case 19US040414). No further medical information is expected.
08-Jul-2019	UAE; 19US040390; -; U.S.A	Species: Canine Breed: Yorkshire Terrier Sex: F Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	01-Jan-2019*	02-Jan-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 8 Jul 2019, the pet owner reported the following event for a female, Yorkshire Terrier of further unknown signalment. Unknown dates: Unknown FRONTLINE (lot unknown) (product unsubstantiated) was administered by the reporter to her dog. The route and location of administration is unknown. An unknown duration following product use, on an unknown date, an unknown number of fleas were found on the dog by the reporter. The reporter conveyed that finding fleas on her dog despite unknown FRONTLINE use was a product failure. She also advised that the canine is allergic to flea bites; however, she refused to provide any additional information regarding said statement. On an unknown date after switching her dog to a Seresto collar, the dog recovered. The reporter refused to provide or discuss any and all information regarding her dog, product use, reported flea complaint, internal environment, external environment, and whether there are any other animals in the home. The reporter mentioned the information above at the end of reporting an unknown FRONTLINE lack of efficacy claim for her mother's cat. Please see case 19US039601. No further medical information expected.
03-Jul-2019	UAE; 19US040392; CA; U.S.A	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: 9 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	05-May-2019	19-May-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 3 Jul 2019, the owner reported the following event for a 9* pound feline (all other signalments unknown). 5 May 2019: The owner purchase a 6 pack FRONTLINE PLUS CATS (S40117AW). One vial was applied between the shoulder blades for the very first time. 19 May 2019: The owner found fleas on the cat. 5 Jun 2019: Another vial was applied. The owner started to note fleas in the household. 3 Jul 2019: The issue is still ongoing. The cat has access to a fenced in yard. There is 1 dog and 1 cat in the household also experiencing an issue with fleas (see case 19US039065, and 19US040375). No further medical information is expected.
09-Jul-2019	UAE; 19US040395;	Species: Feline Breed: Feline	7	7	0	Product used: FIPRONIL	01-Jul-2019	07-Jul-2019	6 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 9 Jul 2019, the owner reported the following event for 7 indoor felines, all other

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 366 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00373

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	NC; U.S.A	(unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown				10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes					signalment unknown. 1 Jul 2019: One vial of the FRONTLINE PLUS CATS (Lot Unknown) was applied topically in between the shoulder blades by the owner. 7 Jul 2019: The owner noticed a small amount of fleas on the pet since applying the product. The cats area strictly indoor and have no access to the outside. The dogs have access to a fenced in yard. Foxes have been noticed in the area. A few indoor fleas have been spotted but the owner thinks these have fallen off of the pets and do not bite him or his wife. This is the first time the owner has noticed fleas on the pets. The owner applies year round on the dogs. There are 2 smaller dogs in the home that are treated with FRONTLINE see additional case 19US039947 and 2 larger dogs that are also treated see additional case 19US040034. No further medical information is expected.
09-Jul-2019	UAE; 19US040398; ID; U.S.A	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: 10 lbs	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	29-Jun-2019	30-Jun-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: Suspected Lack of Efficacy Claim: On 9 Jul 2019, the pet owner reported the following event for two felines who weigh no more than 10 pounds and are of further unknown signalment. 29 Jun 2019: The reporter treated each barn cat for the first time with one vial of FRONTLINE PLUS CATS (S41003). Each vial was applied topically between the shoulder blades and although they are kept strictly outdoors around a barn, it's unknown if fleas were on the cats prior to product use. No further information regarding their external environment could be confirmed. Unknown date: An unknown duration following product application, the reporter observed an unknown number of fleas on both cats. To date, the pet owner continues to find an unknown amount of fleas on the cats and no treatment has been given for either feline. There is a indoor only kitten in the home who is also receiving FRONTLINE PLUS CATS and continues to get fleas. Please see case 19US040015 for details. There is also a dog in the home. The canine is an intact male who weighs 48 pounds and as of 24 Jun 2019 was treated with one chew of Bravecto. Said canine has no contact with either barn cat. No further medical information expected.
10-Jul-2019	UAE; 19US040402; GA; U.S.A	Species: Canine Breed: Rottweiler Sex: M Sex qualifier: Neutered Age: 3.00 Year(s) Weight: 105 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	19-Jun-2019*	08-Jul-2019	19 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 10 Jul 2019, the pet owner reported the following event for Donkey, a 3 year old, 105 pound, male neutered Rottweiler. 19 Jun 2019*: The dog was not having an issue with ticks. 1 vial of FRONTLINE PLUS DOG 89-132 LBS (lot unknown) was applied to the dog in one area between shoulder blades. 8 Jul 2019*: The owner found 3 ticks attached to the dog and removed them. The dog goes out for potty breaks and recreation in the yard. He has not had a bath recently and has not history of skin issues. The owner has been treating monthly since May 2019*. No further medical information is expected.
10-Jul-2019	UAE; 19US040407; TN; U.S.A	Species: Canine Breed: German Shepherd Dog Sex: U Sex qualifier: Unknown	3	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products	01-Jul-2019*	01-Jul-2019*	9 Day(s)	D-D	Suspected Lack of Efficacy: On 10 Jul 2019, the pet owner reported the following event for a German Shepherd, 45 to 88 lbs*, all other signalments unknown the owner did not provide them. 1 Jul 2019*: There were live fleas seen on the dog. 1 vial of FRONTLINE COMBO SPOT ON DOG L (R61508AR) was applied to the dog in one area between the shoulder blades. The owner

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 367 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00374

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: - Weight: 45 - 88 lbs				used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company					was noticing live fleas on the dog daily after the application. The owner purchased a unknown pill to kill the fleas. 10 Jul 2019: The owner saw 2-3 fleas on the dog. The owner has been treating monthly since Jan 2019. The dog goes out for potty breaks and recreation in a year where flea activity has been noted. There is flea activity in the home. There is one other dog in the home having an issue with fleas see case 19US42992. There are 3 dogs that live outdoors who are treated with FRONTLINE whom the owner has not seen fleas on. No further information.
10-Jul-2019	UAE; 19US040411; NJ; U.S.A	Species: Feline Breed: Domestic Longhair (Crossbreed) Sex: F Sex qualifier: Neutered Age: 10.00 Year(s) Weight: 17 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	09-Jul-2019	09-Jul-2019	0 Day(s)	D-D	Suspected Adverse Event: On 10 Jul 2019, the owner reported the following event for Big Mamma, 10 year old, 17 pound, spayed female, Domestic Longhair Feline. 9 Jul 2019: One vial of FRONTLINE PLUS CATS (S40404AW) was applied between the shoulder blades. After an unknown period of time the cat experienced lethargy, and strange behavior. 10 Jul 2019: The cat recovered. The cat received the product 9 Jun 2019 and experienced no issue. No further medical information is expected.
10-Jul-2019	UAE; 19US040412; CA; U.S.A	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: M Sex qualifier: Neutered Age: 10.00 Month(s) Weight: 9.5 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	10-Jul-2019	10-Jul-2019	0 Day(s)	D-C	Suspected Adverse Event: On 10 Jul 2019, the pet owner reported the following event for Remy, a 9.5 pound, 10 month old, male neutered, Domestic Shorthair. 10 Apr 2019: 1 vial of FRONTLINE PLUS CATS (S40301AX) was applied to the cat in one area between the shoulder blades. Shortly after application the cat began twitching, flipping around, blinking excessively. He recovered. 10 Jul 2019: Owner attempted to apply 1 vial of FRONTLINE to the cat. She was able to get a few drops on the cat before he started twitching and blinking excessively before he ran off for 5 minutes. He acted as if he was scared of the owners and then recovered. The owner has been treating with FRONTLINE since March 2019. He was not seen by the veterinarian. It is unknown if the cat was treated in May and June and if a reaction occurred. No further information.
10-Jul-2019	UAE; 19US040414; CA; U.S.A	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: 20.000 lbs	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Overdose)	20-Mar-2019	21-Mar-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 10 Jul 2019, the owner reported the following event for a canine weighing 20 pound (all other signalments unknown). Unknown date: The owner started to notice fleas on the pet. 20 Mar 2019: One vial of FRONTLINE PLUS DOG 23-44 LBS (P61525AL) was applied between the shoulder blades. 21 Mar 2019: The found 6 fleas on the pet. 20 Apr 2019 and 20 May 2019: Another vial was applied. No fleas were noted in the household. 10 Jul 2019: The owner has continued to find fleas daily. The dog has access to a open yard. The dog has received the product seasonally since 2008* with no issue. There is one other dog in the household also experiencing an issue with fleas (see case 19US040389). No further medical information is expected.
11-Jul-2019	UAE; 19US040432; NY; U.S.A	Species: Canine Breed: Pomeranian	1	1	0	Product used: FIPRONIL 10%/S	09-Jul-2019	11-Jul-2019	2 Day(s)	D-D	Suspected Adverse Event: On the 11 Jul 2019, a pet owner reported the following event for Tara, a 17 pound, 7 year old, spayed female, Pomeranian.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 368 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00375

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex: F Sex qualifier: Neutered Age: 7.00 Year(s) Weight: 17 lbs				METHOPRENE 9% SPOT ON Other products used: Cough Tabs; Route: Topical / Cutaneous Was the product used ok?: Yes					9 Jul 2019: The dog started on monthly FRONTLINE PLUS DOG 5-22 LBS (S61902AL), with 1 dose applied topically between the shoulder blades. The owner also administered a Cough Tab to the dog, 1/2 tablet TID. 11 Jul 2019: The dog began to act very nervous, her hind legs were shaking and she had soft stools. The pet owner treated with dog with Cough Tabs. The dog is getting better but has not recovered in full. The dog has a history of a collapsed trachea, which the owner treats with Cough Tabs, 1/2 tablet, PO, TID. The dog has been taking the Cough Tabs for 1 year. The owner stated that every time the dogs trachea collapses he has these same symptoms but she is not sure if it is due to the collapsed trachea or do to the FRONTLINE. No further medical information expected.
11-Jul-2019	UAE; 19US040433; -, U.S.A	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: M Sex qualifier: Neutered Age: 4.00 Year(s) Weight: 11 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	02-Jul-2019	11-Jul-2019	9 Day(s)	D-C	Suspected Adverse Event and Suspected Lack of Efficacy Claim : On 11 Jul 2019, animal owner reported the following event for Fluffy, a 11 pound, 4 year old, neutered male domestic shorthair cat. Apr 2019: The pet owner saw fleas on her cat. 02 Jul 2019: The pet owner applied the full contents of FRONTLINE PLUS CATS (Lot unknown) topically between the shoulder blades for the first time. 11 Jul 2019: The pet owner stated her cat has sores all over the body and at the application site, scratching excessively, and is unable to urinate and defecate. The cat is vocal. The pet owner stated the cat is covered with fleas. There is one other cat in the home but owner would not provide information about that cat. The owner stated she previously used an unknown flea collar for an unknown amount of time. The home has previously been treated with a 3 and 1 carpet powder for fleas and ticks and also using Pet fresh. The pet owner stated she uses tweezers to pull off the fleas on her cat. No further information expected.
11-Jul-2019	UAE; 19US040445; -, U.S.A	Species: Canine Breed: Canine (unknown) Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: Unknown Flea and Tick Treatment; Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	27-Jun-2019*	10-Jul-2019*	12 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 11 Jul 2019, the pet owner reported the following event for a male canine of further unknown signalment. 27 May 2019*: The pet owner treated the dog with an unknown flea and tick treatment. 27 Jun 2019*: The pet owner applied half of the contents of 1 vial of FRONTLINE PLUS DOG 45-88 LBS (S6D24HAX) topically between the shoulder blades for the first time. 28 Jun 2019*: The owner applied 1 full vial of FRONTLINE PLUS topically between the shoulder blades. 06 Jul 2019*: The dog got into water. 10 Jul 2019*: The owner picked off 10 live fleas from the dog. Owner says the dog is scratching due to the fleas. There is also a cat that is mainly outdoors but the owner hasn't seen any issues with the cat and it is also on FRONTLINE PLUS CATS (lot unknown). The owner has received several flea bites as well. The dog stays out longer than just to go to the bathroom and they have an invisible fence. There are trees and wildlife in their environment. Owner is vacuuming daily. Owner was not seeing fleas before the use of FRONTLINE PLUS. No further medical information expected. UPDATE 15 Jul 2019: The pet owner has continued to see her dog scratching and upon examination, her dog still has fleas. 15 Jul 2019: Another dose of FRONTLINE PLUS 45-88 LBS has

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 369 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00376

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											been applied directly on the skin between the shoulder blades. No further medical information expected.
09-Jul-2019	UAE; 19US040482; OH; U.S.A	Species: Canine Breed: Retriever (Golden) Sex: M Sex qualifier: Neutered Age: 4.00 Year(s) Weight: 78 - 79 lbs*	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: Dawn; Route: Topical / Cutaneous Was the product used ok?: Yes	26-Jun-2019	09-Jul-2019*	13 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 9 Jul 2019, the pet owner reported the following event for Buddy, a 78 to 79 pound*, 4 year old, male neutered, Retriever Golden. 25 Jun 2019*: The owner bathed the dog in Dawn to kill fleas. 26 Jun 2019: 1 vial of FRONTLINE PLUS DOG 23-44 LBS(S60801AL) was applied to the dog in one area between the shoulder blades. 9 Jul 2019: The owner saw 5 fleas on the dog and a lot of flea dirt. The owner has been treating the dog with FRONTLINE monthly year round since 2015*. The dog goes out for potty breaks and recreation in a yard with an electric fence, no urban wildlife seen. There are no fleas in the home biting the humans. There is one other dog in the home who was treated with FRONTLINE see case 19US039856. No further information.
11-Jul-2019	UAE; 19US040483; -; U.S.A	Species: Canine Breed: Siberian Husky Sex: M Sex qualifier: Neutered Age: 9.00 Year(s) Weight: 130 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	03-May-2019	15-May-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 11 Jul 2019, the pet owner reported the following event for White Cloud, a 9 year old, 130 pound, neutered male, Golden Retriever/Siberian Husky mix. Unknown dates: As a puppy, White Cloud began receiving one vial of FRONTLINE PLUS DOG 89-132 LBS (FL+) (lot unknown) applied topically between the shoulder blades. One vial has since been applied in the same manner on unknown dates, seasonally. 3 Dec 2018: The reporter administered the first vial of FL+ (S62904) of the season and has continued to administer one vial monthly on the third. 15 May 2019*: The reporter began seeing thousands of fleas on White Cloud at which time, he also saw the canine biting and scratching all over. As a result, he has since bathed White Cloud with Enforcer dog shampoo every 3 days. 3 Jun 2019: One vial of FL+ was applied. Unknown dates: The reporter began finding an unknown quantity of fleas getting onto him. White Cloud was always in close proximity when the reporter was finding fleas on his person. He further suspects he may have an internal flea life cycle likely due to the frequency in which he's bathed the dog since first finding fleas on him. Presently, he continues to find thousands of fleas on White Cloud and an unknown number of fleas on his person and throughout the home. There are no other pets in the home; however, the reporter lives on 35 acres where there is lots of wildlife. He recently found 4 stray cats which have since been removed from the property. White Cloud has access to five acres surrounding the house and that area is manicured, but not fenced. The pet owner is also vacuuming three times daily in an effort to get rid of any potential internal flea lifecycle. White Cloud has a history of experiencing undefined shaking, diarrhea, and emesis following pyrantel and unknown vaccinations. No further medical information expected.
11-Jul-2019	UAE; 19US040489; NY; U.S.A	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: 5 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products	01-Jan-2019	02-Jan-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 11 Jul 2019, the owner reported the following event for a 5 pound feline (all other signalments unknown). 2009*: Started on year round, monthly doses of FRONTLINE PLUS CATS (S40606) topically between the shoulder blades, by the owner. 1 Jan 2019: Another dose of FRONTLINE was applied. Jan 2019*: The owner started seeing fleas on the cat an unknown

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 370 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00377

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Route: Topical / Cutaneous Was the product used ok?: Yes					amount of time after the application. The owner continued to apply the product monthly. 1 Jul 2019: Most recent dose of FRONTLINE was applied. The owner is still seeing a large amount of fleas on the cat. The owner is not seeing fleas in the home. The cat is strictly indoor. There is also a dog in the home treated with FRONTLINE (see case 19US040516). No further medical information expected.
11-Jul-2019	UAE; 19US040510; IL; U.S.A	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: M Sex qualifier: Neutered Age: 15.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	31-May-2019	06-Jun-2019	6 Day(s)	D-C	Suspected Adverse Event: On 11 Jul 2019, the owner reported the following event for Mr. Leo, 15 year old, neutered male, Domestic Shorthair Feline (weight unknown). 31 May 2019: One vial of FRONTLINE PLUS CAT (lot unknown) was applied between the shoulder blades. 6 Jun 2019: The cat experienced hair loss and a hotspot at the application site. The pet did not present the clinic and no treatment was provided. 11 Jul 2019: The symptoms have improved but are still ongoing. The cat has received the product before in the past with no issue. No further medical information is expected.
11-Jul-2019	UAE; 19US040516; NY; U.S.A	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: 50 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-Jan-2019*	02-Jan-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 11 Jul 2019, the owner reported the following event for a 50 pound canine (all other signalments unknown). 2009*: Started on year round, monthly doses of FRONTLINE PLUS DOG 45-88 LBS (lot unknown) topically between the shoulder blades, by the owner. 1 Jan 2019: Another dose of FRONTLINE was applied. Jan 2019*: The owner started seeing fleas on the dog an unknown amount of time after the application. The owner continued to apply the product monthly. 1 Jul 2019: Most recent dose of FRONTLINE was applied. The owner is still seeing a large amount of fleas on the dog. The owner is not seeing fleas in the home. The dog goes outside for potty breaks in a fenced in yard with a deck. There is also a cat in the home treated with FRONTLINE (see case 19US040489). No further medical information expected.
11-Jul-2019	UAE; 19US040537; OH; U.S.A	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON; Route: Topical / Cutaneous Was the product used ok?: Yes	01-Aug-2019	02-Aug-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 11 July 2019, the owner reported the following event for 2 canines (all other signalments unknown). 1 June 2019: The dogs started on FRONTLINE PLUS on a monthly basis. 1 July 2019: The most recent vial of FRONTLINE PLUS DOG 89-132 LBS (S62904AX) and FRONTLINE PLUS DOG 5-22 LBS (S61412AL) was applied between the shoulder blades, by the pet owner. The dogs received 1 vial of each weight category of the FRONTLINE PLUS. It is unknown if fleas were seen at time of application. 2 July 2019*: The dogs had a large amount of fleas. The dogs do not get bathed. The owner stated that is no sign of flea activity in the home. The owner treated the yard with an unknown spray. The dogs go outside for bathroom breaks in an unknown area. No further medical information is expected. UPDATE 2 AUG 2019: 1 Aug 2019: The most recent dose was administered topically, in between the shoulder blades.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 371 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00378

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											2 Aug 2019: The owner is still seeing a large amount of fleas on both dogs. No further medical information is expected. UPDATE 22 Oct 2019: Per a call from the pet owner, she has a 195 lb dog and a dog that is smaller, less than 22 lbs. It is unknown which of the products the dogs are receiving or the amount of product applied, as the pet owner was unreceptive to answering further questions. No further medical information is expected.
11-Jul-2019	UAE; 19US040561; GA; U.S.A	Species: Canine Breed: Coonhound (Black And Tan) Sex: F Sex qualifier: Neutered Age: 4.00 Year(s) Weight: 90 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	26-Jun-2019	09-Jul-2019*	13 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 11 Jul 2019, the pet owner reported the following event for an Unknown name, a 4 year old*, 90 pound, spayed female, coonhound. 26 Jun 2019: The patient received FRONTLINE PLUS DOG 89-132 LBS (S60111AR). The dog has been on FRONTLINE PLUS for 2 years monthly. The owner has always applied FRONTLINE correctly. 9 Jul 2019*: The owner noticed fleas, and the dog was itching. The owner stated he does not give the dog any other products either. The dog is an outdoor dog, and has access to the yard all day. While the dog is the only dog in the area, there are wild animals in the area as well. There are no fleas in the house or on the owner. The owner does treat the area with Seven Dust and does plan to see if it is ok to use on animal. The patient's current condition is ongoing. No further medical information expected. UPDATE 29 Jul 2019: Owner still continuing to see fleas. No further medical information expected.
11-Jul-2019	UAE; 19US040576; CA; U.S.A	Species: Canine Breed: Spaniel (English Springer) Sex: F Sex qualifier: Neutered Age: 15.50 Year(s) Weight: 38 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	05-Jul-2019	06-Jul-2019	1 Day(s)	D-D	Suspected Adverse Event: On 11 Jul 2019, the pet owner reported the following event for Bailey, a 15.5 year old*, 38 pound, spayed female English Springer Spaniel. Unknown date, years ago: The dog began receiving FRONTLINE PLUS DOG 23-44 LBS (lot unknown). 5 Jul 2019: The dog received FRONTLINE PLUS for the first time this year. The product was applied directly on the skin between the shoulder blades. Fleas were not present at the time of application. 6 Jul 2019: The dog began experiencing vomiting and diarrhea. The dog has not presented to the veterinary clinic. The dog was treated at home with Cerenia and metronidazole. The pet owner also bathed the dog using Dawn to remove the product. 11 Jul 2019: The dog's current condition is unknown. The dog was diagnosed with a splenic tumor approximately 3 months ago. No further diagnostics have been performed to determine possible malignancy.No further medical information expected.
11-Jul-2019	UAE; 19US040591; OH; U.S.A	Species: Canine Breed: Scottish Terrier Sex: M Sex qualifier: Neutered Age: 1.50 Year(s) Weight: 19 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	02-Jul-2019	03-Jul-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 11 Jul 2019, the owner reported the following event for Angus, 1.5 year old, weighing 19 pounds, male neutered, Scottish Terrier. 2 Jul 2019: One vial of the FRONTLINE PLUS DOG 5-22 LBS (R61009) was applied topically in between the shoulder blades by the owner. Jul 2019*: The groomer noticed 4 ticks on the pet 2 large and engorged and 2 crawling through the coat. The pet is indoor mostly and goes outside for potty breaks. The pet has access to an open yard and walked on a leash through the park. This is the first time the owner has ticks on the pet. The owner has used FRONTLINE on a seasonal basis staring in the beginning of spring. No further medical information is expected.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 372 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00379

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
11-Jul-2019	UAE; 19US040603; CA; U.S.A	Species: Canine Breed: Retriever (Golden) Sex: U Sex qualifier: Unknown Age: - Weight: 45.0 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	15-Jun-2019	16-Jun-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 11 Jul 2019, the owner reported the following event for an unknown Golden Retriever Mix, weighing 45 pounds, all other signalment unknown. 15 May 2019: One vial of the FRONTLINE PLUS DOG 45-88 LBS (Lot unknown) was applied topically in between the shoulder blades by the owner. 15 Jun 2019: One vial of the FRONTLINE PLUS DOG 45-88 LBS (Lot unknown) was applied topically in between the shoulder blades by the owner. 16 June 2019: The owner noticed a moderate amount of fleas on the pet. The dogs are indoor/outdoor. The dogs have access to a fenced in yard. Fleas were noticed for a week prior to use of FRONTLINE. There is one other pet within the home that is also experiencing issues 19US040580.No further medical information is expected.
11-Jul-2019	UAE; 19US040607; IN; U.S.A	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: M Sex qualifier: Neutered Age: 13.00 Year(s) Weight: 15 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	26-May-2019	28-May-2019	2 Day(s)	D-C	Suspected Adverse Event: On 11 Jul 2019, attending veterinarian reported the following event for Jersey, a 13 year old, 15 pound, neutered male domestic shorthaired cat. 26 May 2019: The pet owner applied FRONTLINE PLUS CATS (Lot unknown) topically at the base of neck. 28 May 2019: The pet presented for burns at the applications site. The cat was treated with antibiotics and steroids. It is unknown if the cat recovered and the application process is unknown. The vet did not have any additional information. No further information expected.
11-Jul-2019	UAE; 19US040635; MI; U.S.A	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: M Sex qualifier: Neutered Age: 3.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	04-Jul-2019	11-Jul-2019	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: 11 Jul 2019: An owner reported the following event in Arlo; a 3 year old, unknown weight, neutered, male, Domestic Shorthair, indoor-outdoor cat in the country. 04 Jul 2019: The owner administered one dose of FRONTLINE PLUS CATS (S41108AW) topically between the shoulders. No fleas were seen at the time of the application. The owner applies the product monthly for at least a year. 11 Jul 2019: The owner saw a large amount of fleas on the cat. There are no other animals in the home. No further medical information expected.
11-Jul-2019	UAE; 19US040647; -; U.S.A	Species: Feline Breed: Feline (unknown) Sex: M Sex qualifier: Unknown Age: - Weight: 11 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous	01-May-2018*	01-Dec-2018*	0 Day(s)	D-D	Suspected Adverse Event: On 11 Jul 2019, the owner reported the following event for an 11 pound, male feline (all other signalments are unknown). Unknown date: The cat started on monthly doses of FRONTLINE PLUS CATS (lot unknown) topically between the shoulder blades by the owner. An unknown amount of time after the application the cat lost fur at the application site. The owner mentioned this happened each time she applied the product. It is unknown if the cat recovered. The owner had problems using FRONTLINE GOLD as well (see case

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 373 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00380

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Was the product used ok?: Yes					19US040592). No further medical information expected.
11-Jul-2019	UAE; 19US040669; OH; U.S.A	Species: Canine Breed: Dachshund Sex: M Sex qualifier: Neutered Age: 8.00 Year(s) Weight: 22 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-Jun-2019	04-Jun-2019*	3 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 11 Jul 2019 the pet owner reported the following event for Buddy, an 8 year old (born *1 Jan 2011), 22 pound, neutered male Dachshund. 1 Jun 2012*: The canine started on FRONTLINE PLUS DOG 23-44 LBS (lot and expiration unknown), 1 vial topically, in between the shoulder blades, once monthly. 1 Jun 2019: One dose was applied. No fleas were noted on the canine at the time of application. 4 Jun 2019*: The pet owner began seeing a small amount of fleas on the canine but none in the environment. 1 Jul 2019: The most recent dose was applied. 12 Jul 2019: The pet owner continues to see a small amount of fleas on the canine but none in the environment. The canine spends the majority of the time inside the home with access to the lawn outside. The pet owner states there is another canine nearby that has fleas and believes her pet is obtaining the fleas from there. There are no other pets in the home. No further medical information is expected.
11-Jul-2019	UAE; 19US040672; MI; U.S.A	Species: Canine Breed: Schnauzer Sex: F Sex qualifier: Neutered Age: 3.00 Year(s) Weight: 22.4 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	17-Nov-2018	11-Jul-2019	7 Month(s) 3 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 11 Jul 2019, the owner reported the following event for Indie, 3 year old, 22.4 pound, spayed female, Schnauzer canine. 17 Nov 2018: One vial of FRONTLINE PLUS DOG 5-22 LBS (lot unknown) was applied between the shoulder blades. It is unknown if the dog received the product prior. 11 Jul 2019: The dog tested positive for anaplasmosis vis 4DX. The pet was treated with Doxycycline. No further medical information is expected. UPDATE 16 Jul 2019: Per medical record the owner purchased 3 doses of FRONTLINE on 15 Nov 2018. No further medical information is expected.
11-Jul-2019	UAE; 19US040695; -; U.S.A	Species: Canine Breed: Retriever Labrador Sex: F Sex qualifier: - Age: 2.00 Year(s) Weight: 70 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	07-Jul-2019	07-Jul-2019	0 Day(s)	D-C	Suspected Adverse Event: On 11 Jul 2019, animal owner reported the following event for Shadow, a 2 year old, 70 pound, intact female labrador retriever. 07 Jul 2019, The pet owner applied the full contents of 1 vial of FRONTLINE PLUS DOG 45-88 POUND (Lot unknown) topically between the shoulder blades for the first time. The dogs skin became irritated at the application site within 2 hours. 08 Jul 2019: The application site became inflamed. The pet owner contacted the vet who advised to rinse the area and apply neosporin. 11 Jul 2019: The dog presented for an exam due to the application site developing alopecia and looks like the skin is burned and sloughing off. The dog had not been treated with anything at the time of the call. The owner declined providing any additional details. No further information expected.
11-Jul-2019	UAE; 19US040703; GA; U.S.A	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier:	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON	15-Jun-2019	11-Jul-2019	26 Day(s)	D-D	Suspected Adverse Event: 11 Jul 2019: An owner reported the following event in a 20 pound dog with unknown signalment. 15 Jun 2019: The owner administered one dose of FRONTLINE PLUS DOGS 5-22 LBS (lot unknown, package unavailable) topically between the shoulders. No fleas were seen at the time of

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 374 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

v1.2

ED_005739D_00014390-00381

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Unknown Age: - Weight: 20 lbs				Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes					the application. The owner applies the product monthly for an unknown amount of time. 11 Jul 2019: The owner says the dog is itching. The fur is too thick to see fleas but the owner believes the itching is from fleas. There is one other dog in the home that is not itching. No further medical information expected.
11-Jul-2019	UAE; 19US040713; -; U.S.A	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	4	4	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	01-May-2019*	01-Jun-2019*	N/A	D-D	Suspected Lack Of Efficacy Claim: On 11 Jul 2019, the owner reported the following event for 4 unknown canines, all other signalment unknown. Unknown date: One vial of FRONTLINE PLUS DOG * (unsubstantiated) was applied topically in between in an unknown location by the owner, the purchase history in unknown at this time. It is unknown how long the owner has been seeing fleas or if fleas were seen prior to treatment. The owner has applied the product 3 times once monthly from an unknown start date. The owner has treated the home previously about 6 weeks ago. There is 1 cat within the home also experiencing flea issues see case 19US042101 No further medical information expected at this time.
12-Jul-2019	UAE; 19US040726; MI; U.S.A	Species: Feline Breed: Manx Sex: F Sex qualifier: - Age: 13.00 Month(s) Weight: 5 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	12-Jul-2019	12-Jul-2019	0 Day(s)	D-D	Suspected Adverse Event: On 12 Jul 2019 the pet owner reported the following event for Pippa a 13 month old, 5 pound intact female Manx and Domestic Shorthair Mix. 12 Jul 2019: The owner applied the FRONTLINE PLUS CATS (S40815AW) to the skin between the shoulder blades for the first time ever. Within 10 minutes the cat licked off the product and immediately began drooling. The cat did not present to the vet clinic and the symptoms are ongoing. No further medical information expected.
12-Jul-2019	UAE; 19US040756; MI; U.S.A	Species: Canine Breed: Retriever (Golden) Sex: M Sex qualifier: Neutered Age: 12.00 Year(s) Weight: 80 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	11-Jul-2019	12-Jul-2019	1 Day(s)	D-D	Suspected Adverse Event: 12 Jul 2019: An owner reported the following event in Chance; a 12 year old, 80 pound, neutered, male, Golden Retriever. 03 Jun 2019: The owner administered one FRONTLINE PLUS DOGS 45-88 LBS (S61603) topically between the shoulder blades for the first time. 07 Jun 2019: The dog exhibited vomiting and diarrhea. The vomiting stopped that day. 12 Jun 2019: The dog fully recovered. 11 Jul 2019: The owner applied one dose topically between the shoulder blades. 12 Jul 2019: The dog exhibited diarrhea. No treatments were administered and the status is unknown. No further medical information available.
12-Jul-2019	UAE; 19US040771; PA; U.S.A	Species: Canine Breed: Shar Pei Sex: F Sex qualifier: Neutered Age: 9.00 Year(s)	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products	01-Jul-2018	12-Jul-2019	11 Day(s)	D-D	Suspected Lack of Efficacy Claim: 12 Jul 2019: An owner reported the following event in Nikkie Soo; a 9 year old, 48 pound, spayed, female, Shar Pei, indoor-outdoor, in a wooded area. 01 May 2019 and 01 Jun 2019: The owner administered FRONTLINE PLUS DOGS 45-88 LBS (S6211AL) one dose topically between the shoulders as part of a yearly, monthly

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 375 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00382

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: 48 lbs				used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes					preventative. 07 Jun 2019: The owner saw an unknown amount of fleas on the dog and had some jump on her. 01 Jul 2019: The owner administered one tube topically between the shoulders. 12 Jul 2019: The owner saw 22 live fleas on the dog. The owner bathes the dog in Dawn and Sergeants flea and tick up to 2 times a month. There is an indoor cat in the home (case 19US040785). No further medical information expected.
12-Jul-2019	UAE; 19US040785; PA; U.S.A	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: F Sex qualifier: Neutered Age: 13.00 Year(s) Weight: 6 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-Jul-2018	12-Jul-2019	11 Day(s)	D-D	Suspected Lack of Efficacy Claim: 12 Jul 2019: An owner reported the following event in Spookie; a 13 year old, 6 pound, spayed, female, domestic short hair, indoor only cat. 01 May 2019 and 01 Jun 2019: The owner administered one FRONTLINE PLUS CATS (S40815BW) topically between the shoulders as part of a year round, monthly preventative. 07 Jun 2019: The owner saw an unknown amount of fleas on the cat using a flea comb and had some jump on her. 01 Jul 2019: The owner administered one tube topically between the shoulders. 12 Jul 2019: The owner saw an unknown amount of live fleas on the cat. The owner bathes the cat in Dawn and Sergeants flea once a month. There is an indoor-outdoor dog in the home (case 19US040771). No further medical information expected.
12-Jul-2019	UAE; 19US040786; CA; U.S.A	Species: Canine Breed: Dachshund (Miniature) Sex: M Sex qualifier: Neutered Age: 11.00 Year(s) Weight: 12 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	11-Jul-2019	11-Jul-2019	6 hours*	D-D	Suspected Adverse Event: On 12 Jul 2019, the pet owner reported the following event for Dieter, an 11 year old*, 12 pound, neutered male Miniature Dachshund. Unknown date, Jan 2019*: The dog began receiving FRONTLINE PLUS DOG 5-22 LBS (P61525AL). 11 Jul 2019: The most recent date of application, which was the first application this year. Within 6 hours, the dog began experiencing restlessness, anxiety, and was constantly begging the pet owner to go outside. The dog has not presented to the veterinary clinic. The dog was treated with an unknown homeopathic medication and tramadol. The dog's current condition is ongoing. The dog previously received FRONTLINE PLUS on unknown dates in previous years with no previous adverse effects. No further medical information expected.
12-Jul-2019	UAE; 19US040792; PA; U.S.A	Species: Canine Breed: German Shepherd Dog Sex: M Sex qualifier: - Age: 13.00 Week(s) Weight: 38 lbs	3	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	17-Jun-2019	12-Jul-2019	25 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 12 Jul 2019 the pet owner reported the following event for an unknown 13 week old 38 pound intact male German Shepherd Dog. 17 Jun 2019: The owner applied 1 vial of FRONTLINE PLUS DOG 23-44 LBS to the skin between the shoulder blades for the first time. The owner was not seeing fleas at the time of the application. 12 Jul 2019: The owner noticed fleas on the dog. There 2 other dogs in the home using NEXGARD with no issues with fleas. The owner is not noticing indoor flea activity. No further medical information expected.
12-Jul-2019	UAE; 19US040835; VA; U.S.A	Species: Feline Breed: Domestic Shorthair (Crossbreed)	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE	01-Jul-2019	05-Jul-2019*	4 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 12 Jul 2019, the pet owner reported the following event for Lucy, a 9 year old*, 5 pound*, spayed female, Domestic Shorthair. Unknown dates: The pet owner applied one vial of FRONTLINE

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 376 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00383

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex: F Sex qualifier: Neutered Age: 9.00 Year(s) Weight: 5 lbs				12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes					PLUS CATS (lot unknown) topically between the shoulder blades. One vial has since been applied in the same fashion, seasonally. 1 Jul 2019: One vial of FRONTLINE PLUS CATS (M40605AW) was applied. It was the first application of the season and at the time of application, no fleas were present on the cat or in the home. 5 Jul 2019*: The reporter and his wife began finding 'a good amount' of fleas on Lucy. The reporter couldn't further describe the quantity of fleas seen on the cat, but has observed her itching and scratching all over. Presently, they continue to find an unknown quantity of fleas of Lucy though they are not finding any fleas in the home. Lucy is kept primarily indoors, but about once monthly, she goes out on the sidewalk for about one to three minutes 'just to experience the outdoors' and then goes right back inside. It cannot be confirmed when she was last outside prior to the reporter finding fleas on her. No information regarding the external environment could be obtained because the reporter had to disconnect the call. There are no other pets in the home. No further medical information expected.
12-Jul-2019	UAE; 19US040836; -; U.S.A	Species: Canine Breed: Shih Tzu Sex: F Sex qualifier: Neutered Age: 2.00 Year(s) Weight: 20 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	26-Jun-2019	28-Jun-2019	2 Day(s)	D-D	Suspected Adverse Event: On 12 Jul 2019, animal owner reported the following event for Harvey, a 2 year old, 20 pound, spayed female, Shih Tzu. Oct 2018: Started monthly FRONTLINE PLUS DOG 5-22 LBS (UNKNOWN) topically between the shoulder blades for the first time. 26 Jun 2019: A dose was applied. 28 Jun 2019: The pet owner is noticing the dog is scratching excessively. The scratching is ongoing at time of the report. The owner has not seen fleas and the dog has not had veterinary care. No further information expected.
12-Jul-2019	UAE; 19US040861; -; U.S.A	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: 80 - 110 lbs	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	10-Jul-2019	11-Jul-2019*	1 Day(s)	D-D	Suspected Adverse Event: On 12 Jul 2019, the owner reported the following event for two canines 80 and 110 pounds (all other signalments unknown). 10 Jul 2019: First dose of the season of FRONTLINE PLUS DOG 89-132 LBS (R60908BR) was applied topically between the shoulder blades, by the owner. The dogs had some scratching prior to the application Unknown date: The dogs started scratching more than before the application. The owner is not seeing an fleas on the dog or in the house. The owner has used FRONTLINE before last year, for an unknown amount of time with no problems. The owner switched to a different product but was treating year round. The dogs go outside for potty breaks in a fenced in yard with trees. No further medical information expected.
12-Jul-2019	UAE; 19US040894; IL; U.S.A	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products	01-Jul-2019*	02-Jul-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 16 Jul 2019 the pet owner reported the following event for two canines of unknown signalment. Unknown date: Started on FRONTLINE PLUS 5-22 LBS (lot number unknown), 1 dose topically, between the shoulder blades. 1 May 2019*: The pet owner began applying Advantage Multi to the two canines. 15 May 2019*: The pet owner began seeing an unknown number

N/A signifies the information for this field is either not available or not applicable

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

Report printed on 25-Oct-2019 at 8:39:59PM

*indicates Approximate date or weight

Page 377 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00384

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Route: Topical / Cutaneous Was the product used ok?: Yes					of fleas on both canines. 1 Jul 2019*: The pet owner applied the most recent dose of FRONTLINE PLUS to both canines. 2 Jul 2019*: An unknown number of fleas were noted on both canines. 12 Jul 2019: The pet owner reported that she is no longer seeing fleas on either canine. The two canines spend the majority of the time inside the home with access to an outside lawn. There are no other pets in the household. No further medical information is expected.
12-Jul-2019	UAE; 19US040964; GA; U.S.A	Species: Canine Breed: Boxer Sex: M Sex qualifier: Neutered Age: 6.00 Year(s) Weight: 89 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	11-Jul-2019	11-Jul-2019	0 Day(s)	D-C	Suspect Adverse Event: On 12 Jul 2019, an owner reported the following event for Buddy, a 6 year old*, 89 pound, neutered male, Boxer, Pit Bull, and Hound Mix. 11 Jul 2019: One vial of FRONTLINE PLUS FOR DOGS 89-132 LBS (lot unknown) was applied between the shoulder blades. Within 30 minutes after product application the dog began to pant excessively, stared at the wall, and could not walk due to pain. 12 Jul 2019: The dog presented to the veterinarian. The veterinarian treated with an injection of Rimadyl for the dogs' pain. The veterinarian stated the event could be a possible reaction to FRONTLINE and expects it to slowly resolve within a week. Owner believes dog is improving, but event is not resolved. The dog has no history of reactions. The dog was in good health prior to this event but did see a veterinarian at an unknown time for pulling a muscle. No further medical information expected.
12-Jul-2019	UAE; 19US040985; MI; U.S.A	Species: Canine Breed: German Shepherd Dog Sex: M Sex qualifier: - Age: 13.00 Year(s) Weight: 80.000 lbs*	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	10-Jul-2019	12-Jul-2019	2 Day(s)	D-D	Suspect Adverse Event: On 12 Jul 2019, the owner reported the following event for Coleman, a 13 year old*, 80 pound*, intact male, German Shepherd Dog. 2018*: The dog had surgery for removal of bladder stones. 10 Jul 2019: One vial of FRONTLINE PLUS FOR DOGS 45-88 LBS (lot unknown) was applied between the shoulder blades for the first time. 12 Jul 2019: The dog vomited in the morning and is not eating, drinking, or going to the bathroom. The dog attempts to urinate. The dog has not been seen by the veterinarian. No further medical information expected.
12-Jul-2019	UAE; 19US041002; -, U.S.A	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: 8.00 Week(s) Weight: Unknown	2	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	12-Jul-2019	12-Jul-2019	0 Day(s)	D-D	Suspected Adverse Event: On 12 Jul 2019, the pet owner reported the following event for an approximately 8 week old, intact, feline of further unknown signalment. 12 Jul 2019: The reporter applied one vial of FRONTLINE PLUS CATS (lot unknown) topically between the shoulder blades, but the kitten who is feral was very wiggly during application and subsequently ingested an unknown volume of product. Not long following accidental product ingestion, the kitten began hypersalivating. It's unknown if treatment was administered for the ongoing event. There are an unknown number of feral kittens from the same litter that received the product and presumably are doing well. The reporter declined to provide additional details. No further medical information expected.
10-Jul-2019	UAE; 19US041028; NJ; U.S.A	Species: Canine Breed: Small crossbred (<10	1	1	0	Product used: FIPRONIL 10%/S	06-Jul-2019	07-Jul-2019	1 Day(s)	D-D	Suspected Adverse Event: On 10 Jul 2019 the following event was reported to Safety Call International (SCI) by the pet owner for Bella an 11 year old 21.6 pound female spayed Small crossbred

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 378 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

v1.2

ED_005739D_00014390-00385

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		(Kg) Sex: F Sex qualifier: Neutered Age: 11.00 Year(s) Weight: 21.6 lbs				METHOPRENE 9% SPOT ON Other products used: IVERMECTIN/PYRANTEL PAMOATE CHEWABLE 68MCG/163MG; Route: unknown Was the product used ok?: Unknown to Company					(<10 kg). 6 Jun 2019: The owner applied an unknown amount of FRONTLINE PLUS DOG 5-22 LBS (UNKNOWN) to the dog in an unknown manner. It is unknown if this is the first application. 7 Jun 2019: The owner administered an unknown amount of HEARTGARD PLUS (68 MCG/57 MG) (6BC0770, NOV 2019) PO. It is unknown if this is the first administration. 3 hours later the dog appeared to have a bloated stomach and was crying. Then shortly afterward the dog had vomiting and diarrhea. The owner called the veterinarian and gave the dog an unknown amount of Pepto Bismol. An unknown amount of time later the symptoms resolved. 6 Jul 2019: The owner applied an unknown amount of FRONTLINE PLUS DOG 5-22 LBS (UNKNOWN) to the dog in an unknown manner. 7 Jul 2019: The owner administered an unknown amount of HEARTGARD PLUS (68 MCG/57 MG) (6BC0770, NOV 2019) PO. 3 hours later the dog appeared to have a bloated stomach and was crying. Then shortly afterward the dog had vomiting and diarrhea. The owner called the veterinarian and gave the dog an unknown amount of Pepto Bismol. An unknown amount of time later the symptoms resolved. No further medical information expected.
15-Jul-2019	UAE; 19US041042; PA; U.S.A	Species: Canine Breed: Yorkshire Terrier Sex: F Sex qualifier: Neutered Age: 2.00 Year(s) Weight: 5 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	10-Jul-2019	10-Jul-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 15 Jul 2019, a pet owner reported the following event for Katie, a 2 year old, 5 pound, spayed female Yorkshire Terrier. 2017*: The dog began receiving monthly year round applications of FRONTLINE PLUS DOG 5-22 LBS (Lot Unknown), topically between the shoulder blades in one spot. 10 Jul 2019: The pet owner applied the most recent application of FRONTLINE PLUS DOG 5-22 LBS (S61006AL) 2 days early because the owner found a flea and the dog was scratching. The pet owner has been finding a few live fleas on the dog daily since application. The yard is fenced in and the dog is leash walked only. The pet owner takes the dog to Florida 6 months out of the year from October to April. There are no other pets in the house. No further information expected.
15-Jul-2019	UAE; 19US041053; -; U.S.A	Species: Canine Breed: Chihuahua Sex: F Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	11-Jul-2019	11-Jul-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 15 July 2019, the owner reported the following event for a female, Chihuahua (all other signalments unknown). Unknown date: The dog has not been on any flea preventative this year. It is unknown if any fleas were seen on the pet. 11 July 2019: The first vial of FRONTLINE PLUS DOG 5-22 LBS (S61412AL) was applied between the shoulder blades, by the pet owner. The pet owner saw fleas after application of the product. 12 July 2019: The dog had a moderate amount of fleas. The dog does not get bathed. The owner is not seeing any flea activity in the home. The dog goes out for bathroom breaks. No further medical information is expected.
15-Jul-2019	UAE; 19US041057; -; U.S.A	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown	3	3	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products	01-Jul-2019*	15-Jul-2019*	2 Week(s)	D-D	Suspected Adverse Event: On 15 Jul 2019, a pet owner reported the following event for 3 canines of unknown signalment. Unknown Date: The dogs received an unknown amount of FRONTLINE PLUS DOG (Unsubstantiated) (Lot Unknown) in an unknown manner. It is unknown how long the dogs have been receiving the product.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 379 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00386

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Age: - Weight: Unknown				used: no other products Route: unknown Was the product used ok?: Unknown to Company					Unknown Date: The dogs were scratching. The owner was not seeing fleas. The pet owner declined all other details for the report. No further information.
15-Jul-2019	UAE; 19US041064; -; U.S.A	Species: Feline Breed: Feline (unknown) Sex: F Sex qualifier: Unknown Age: 16.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	11-Jul-2019	12-Jul-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 15 Jul 2019, the owner reported the following event for a 16 year old, female feline (all other signalments unknown). Unknown date: Started on monthly doses of FRONTLINE PLUS CATS (S40606AW) topically, between the shoulder blades, by the owner, on a year round basis. 11 Jul 2019: The owner saw approx. 10 fleas on the cat and applied a dose of FRONTLINE. The product was only given a day before it was actually due for the next dose. 12 Jul 2019*: The owner continued to see fleas on the cat. The owner is not seeing any fleas in the house. The cat goes outside about once every other day in an open yard with trees, bushes, and a porch. The owner also has a dog that is treated with Advantix K9. No further medical information expected.
15-Jul-2019	UAE; 19US041070; KY; U.S.A	Species: Canine Breed: Chihuahua Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	3	3	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	06-Jul-2019	15-Jul-2019	9 Day(s)	D-D	Suspected Lack of Efficacy Claim: On the 15 Jul 2019, a pet owner reported the following event for a total of 3 Chihuahuas of unknown further signalment. 2017*: The dogs started on monthly FRONTLINE PLUS DOG 5-22 LBS (unknown lot number) with 1 dose applied topically between the shoulder blades. The owner applies the product seasonally. The owner has a total of 6 dogs in the home. All of the dogs are on FRONTLINE PLUS only 3 are on the same size of FRONTLINE PLUS the other 3 are larger in size. 6 Jul 2019: The owner applied the first dose of FRONTLINE PLUS of the season. The pet owner was already seeing a medium amount of fleas on the dogs before starting the FRONTLINE PLUS. 15 Jul 2019: The pet owner is still seeing a medium amount of fleas on the dogs. All of the dog are indoor/outdoor. They have access to a backyard with bushes and grass that is not fenced in. The owner does take the dogs to the groomer once a month. The owner is only seeing the fleas on the dogs not inside of the home. The owner reported another case for the other dogs see 19US041059. No further information expected.
15-Jul-2019	UAE; 19US041085; -; U.S.A	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	01-Jul-2019*	15-Jul-2019	2 Week(s)	D-D	Suspected Adverse Event: On 15 Jul 2019, the owner reported the following event for an unknown canine (all signalments unknown). Unknown date: An unknown amount of FRONTLINE (product unsubstantiated) (lot unknown) was given (unknown application). It is unknown if this was the first use of the product. 15 Jul 2019: The dog had a seizure at 3am and then was not moving. The dog was not seen by a veterinarian or given any treatment. The symptoms are ongoing. No further medical information expected.
15-Jul-2019	UAE;	Species: Canine	1	1	0	Product used:	23-Jun-2019	24-Jun-2019	1 Day(s)	D-C	Suspected Adverse Event: On 15 Jul 2019 the pet owner reported

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 380 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00387

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	19US041091; NC; U.S.A	Breed: Retriever Labrador Sex: M Sex qualifier: Neutered Age: 5.00 Year(s) Weight: 50 lbs				FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes					the following event for Moose a 5 year old, 50 pound, male neutered, Retriever Labrador and Blue Heeler mix. 23 May 2019: The owner applied 1 vial of FRONTLINE PLUS DOG 45-88 LBS (S62202AX) to the skin between the shoulder blades for the first time. 24 May 2019: The owner noticed a large open, gaping wound where the product was applied. The wound was bleeding and 3 inches long by 2 inches wide. The dog did not present to the vet clinic and the owner treated with hydrogen peroxide and Neosporin. *7 Jun 2019: The dog recovered. 23 Jun 2019: The dog sitter applied the most recent dose. 24 Jun 2019: The dog sitter noticed a large open, gaping wound where the product was applied. The wound was again bleeding and 3 inches long by 2 inches wide. The dog did not present to the vet clinic and the dog sitter treated the wound with hydrogen peroxide and Neosporin. 7 Jul 2019: The owner picked the dog up and the wound was smaller but not healed. *10 Jul 2019: The dog recovered. No further medical information expected.
14-Jul-2019	UAE; 19US041113; NC; U.S.A	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: F Sex qualifier: Neutered Age: 18.00 Month(s) Weight: 7 lbs	2	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: PO-Oral Was the product used ok?: No (Route not indicated / recommended)	14-Jul-2019	14-Jul-2019	0 Day(s)	D-D	Suspected Adverse Event: On 14 Jul 2019, the following event was reported to Safety Call International (SCI) by the pet owner for Cuddles, an 18 month old, 7 pound, spayed female Domestic Shorthair. 14 Jul 2019: The owner administered 1 dose of FRONTLINE PLUS CATS (M40108AW) orally versus topically. The cat vomited immediately and was slightly lethargic. No treatment was administered. There is another cat in the house that received a dose by mouth that is asymptomatic. No further medical information expected.
15-Jul-2019	UAE; 19US041116; OH; U.S.A	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: F Sex qualifier: Unknown Age: 10.00 Month(s) Weight: 6 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	01-Jul-2019	14-Jul-2019	0 Day(s)	D-D	Suspected Adverse Event and Suspected Lack of Efficacy Claim : On the 15 Jul 2019, a pet owner reported the following event for Little Bit, a 6 pound, 10 month old, intact female, Domestic Shorthair. 24 Jun 2019: The pet owner noticed that the cat had a moderate amount of fleas on her. 1 Jul 2019: The pet owner applied for the first time 1 dose of FRONTLINE PLUS CATS (S40815BW), topically between the shoulder blades because he was seeing a moderate amount of fleas on his cat. This is the only pet the owner has in the household. This is an indoor cat. The owner was only seeing fleas on the cat and not in his home. 14 Jul 2019: The pet owner was still seeing fleas on his cat and the cat was scratching constantly so he applied another dose of the FRONTLINE to the cat. 15 Jul 2019: The pet owner noticed that the cat had scabs on the left upper lip and on her ears from scratching so much. The pet owner has discontinued the use of the product due to the reaction. The issue is ongoing. No further information expected.
15-Jul-2019	UAE; 19US041119;	Species: Feline Breed: Feline	3	3	0	Product used: FIPRONIL	25-Jun-2019*	27-Jun-2019*	2 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 15 Jul 2019, the pet owner reported the following event for Sunny, a 14 year old, 12 pound,

N/A signifies the information for this field is either not available or not applicable

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

Report printed on 25-Oct-2019 at 8:39:59PM

*indicates Approximate date or weight

Page 381 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00388

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	NJ; U.S.A	various breeds Sex: X Sex qualifier: Neutered Age: 12.00 Month(s) Weight: 5 - 12 lbs				10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes					male neutered, Maine Coon. Ellie, a 3 year old*, 5 pound*, female spayed, Domestic Shorthair. Leah, a 12 month old*, 6 pound*, female spayed, Domestic Shorthair. 25 Jun 2019*: The patients began receiving FRONTLINE PLUS CATS(S41307AW). This was their first dose and no fleas were seen prior to this, and the doses were given between the shoulder blades. 27 Jun 2019*: The owner noticed fleas. The owner stated the cats were being to itch once the fleas arrived. The animals are indoor only, and are not bathed. There are fleas in the household, and they have bitten the owner. No further treatments for the house or the cats has taken place. The patients' current condition is ongoing. There a total of 4 felines in the household. The 6 pack of FRONTLINE was bought from Walmart. With another case for one of the cats, see case 19US042748. No further medical information expected.
15-Jul-2019	UAE; 19US041122; TN; U.S.A	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: F Sex qualifier: Neutered Age: 10.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	01-Jun-2019	02-Jun-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim and Suspected Adverse Event : On 15 Jul 2019, the animal owner reported the following event for Bootsie, a 10 year old*, unknown weight, Domestic Shorthair. 01 Jun 2019: She received FRONTLINE PLUS CATS (H41601AL) one dose applied topically between the shoulders. 02 Jun 2019: The owner noted a large amount of fleas on her. She is also experiencing pruritus. The owner has been noticing fleas off of the pet inside the home. 03 Jun 2019*: The coat at the application site changed to an unknown color. 05 Jun 2019*: She began experiencing alopecia at the application site. She has not presented to the veterinary clinic. No treatments have been performed. 19 Jun 2019*: The alopecia has resolved. She is continuing to experience fleas and pruritus. Her current condition is ongoing. The owner does not bathe the pet. The owner did notice fleas on the pet and inside of the home prior to application. She is indoor only. There are a total of 36 outdoor felines on the property that have not received any monthly flea preventative. No further medical information expected.
15-Jul-2019	UAE; 19US041149; CA; U.S.A	Species: Canine Breed: Border Collie Sex: M Sex qualifier: Neutered Age: - Weight: 45 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: unknown dog shampoo; Route: Topical / Cutaneous Was the product used ok?: Yes	30-Jun-2019	15-Jul-2019	15 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 15 Jul 2019 a pet owner reported the following event for Booger, a 45 pound, neutered male Border Collie with unknown age. 30 Jun 2019: Owner applied 1 vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown) topically to Booger. 15 Jul 2019: Saw 1 live flea on dog. Booger lives outside only, contained within the grassy yard. The owner treated the yard with pesticide on 13 Jul 2019. There is one other animal in the household, a cat, who does not belong to the reporter, and he does not know what the cat is treated with. No fleas in the home. The dog was bathed with an unknown dog shampoo approximately 28 Jun 2019. The owner originally stated he had applied FRONTLINE twice to the dog, with the first time being May 2019, but then later said he uses the product monthly year round. No further medical information expected.
15-Jul-2019	UAE; 19US041169;	Species: Canine Breed: Retriever	1	1	0	Product used: FIPRONIL	15-Jun-2019	08-Jul-2019*	23 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 15 Jul 2019, the animal owner reported the following event for Larry, a 6 year old*, 85.0

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 382 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00389

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
	GA; U.S.A	(Golden) Sex: M Sex qualifier: Neutered Age: 6.00 Year(s) Weight: 85.0 lbs*				10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes					pound*, neutered male Golden Retriever. Jan 2016*: He began receiving FRONTLINE PLUS DOG 45-88 LBS (M63201AR) one dose applied topically monthly year round. 15 Jun 2019: The most recent application. 08 Jul 2019*: The owner noticed flea dirt on the pet. He is pruritic The owner has not been noticing fleas off of the pet inside the home. The dog does frequent grass yard and does go on walks. He has not presented to the veterinary clinic. Treatment was initiated with Capstar. His current condition is ongoing. The owner bathes the pet every other month with an oatmeal based shampoo. There are two indoor only felines in the household that have not had any monthly flea preventative products. No further medical information expected.
15-Jul-2019	UAE; 19US041195; -; U.S.A	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	4	3	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Unknown to Company	10-Jul-2019	11-Jul-2019	1 Day(s)	D-D	Suspected Adverse Event: On 15 Jul 2019 an animal owner reported the following event in 3 canines of unknown signalment. 10 Jul 2019: 4 canines were applied FRONTLINE PLUS 5-22 LB (lot, expiration unknown) for the first time topically between the shoulder blades. 11 Jul 2019: 3 of the 4 canines developed a cough. 15 Jul 2019: The 3 canines are still coughing. Canines were reported to be healthy at time of report. No further information provided nor expected.
15-Jul-2019	UAE; 19US041205; SC; U.S.A	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: F Sex qualifier: Neutered Age: 1.00 Year(s) Weight: 5 - 7 lbs	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	22-May-2019	01-Jun-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 15 Jul 2019, a pet owner reported the following event for Spice, a 1 year old, 5 pound, spayed female Domestic Shorthair and Pickles, a 12 year old, 7 pound, spayed female Domestic Shorthair. 22 Apr 2019: The cats received the first application of FRONTLINE PLUS CATS (S40603AW) of the season, topically between the shoulder blades in one spot. 22 May 2019: The cats received the second application of FRONTLINE. 1 Jun 2019: The pet owner noticed a few live fleas on the cats' ears and stomach. 24 Jun 2019: The most recent application of FRONTLINE was applied. 15 Jul 2019: The pet owner noticed that the cats' stomachs were covered in live fleas. There are 2 dogs in the home that are on NEXGARD (Unsubstantiated) (Lot and Expiration Unknown) and are not having an issue with fleas. The cats live outside and go into a tack room at night to sleep. No further information expected.
15-Jul-2019	UAE; 19US041219; -; U.S.A	Species: Feline Breed: Himalayan Sex: M Sex qualifier: Neutered Age: 5.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous	08-Jul-2019	14-Jul-2019	6 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 15 Jul 2019 an animal owner reported the following event in Marcello, a 5 year old, neutered male, Himalayan Persian. 08 Jun 2019: The feline was applied FRONTLINE PLUS CATS (S40701AW) between the shoulder blades for the first time. There were no fleas seen at time of administration. 08 Jul 2019: The feline was administered 1 vial of FRONTLINE PLUS CATS. 14 Jul 2019: A few fleas were seen on the feline. The cat has access to outdoors. There are no other pets in the

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 383 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).
Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.
Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00390

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Was the product used ok?: Yes					household. No further information provided nor expected.
14-Jul-2019	UAE; 19US041227; IL; U.S.A	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: F Sex qualifier: - Age: 8.00 Week(s) Weight: 2.04 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: PUREVAX FELINE 3 - 16D8.21; Route: Topical / Cutaneous Was the product used ok?: Yes	14-Jul-2019	14-Jul-2019	0 Day(s)	D-C	Suspected Adverse Event: On 14 Jul 2019 an attempting veterinarian contacted Safety Call International (SCI) to report the following event in Louis Turner, an 8 week old, 2.04 pound, intact female, Domestic Shorthair. 14 Jul 2019: The feline was administered FRONTLINE PLUS CATS (P41204) between the shoulders and vaccinated with PUREVAX FELINE 3 (66267A624, expiration unknown). The vaccine was given SC, but the volume and location of administration is unknown. Within 30 minutes of product administration, the feline became frantic after this was done and developed tremors. Pet owner bathed the cat in liquid dish soap and water and presented to emergency veterinary clinic. The cat was reported to be hypothermic on exam and shaking due to being cold, but no further tremors noted in hospital. The veterinarian states cat's Blood Glucose is 308. Cat was admitted for hospitalization. UPDATE 15 Jul 2019 per conversation with clinic : Feline recovered. No further information provided nor expected.
15-Jul-2019	UAE; 19US041230; -; U.S.A	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	01-Jul-2019*	02-Jul-2019	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 15 Jul 2019, the pet owner reported the following event for two cats of unknown signalment. 1 Jul 2019*: The patient began receiving FRONTLINE PLUS CATS (lot unknown). It is unknown if the dose was applied correctly and it is unknown if it is the first time the cats have gotten FRONTLINE. 2 Jul 2019*: The owner noticed fleas. It is unknown if the animals go outside, if they had any other products at the same time, or the environment of the household. The patient's current condition is ongoing. There a total of 2 felines in the household. Further information unknown as owner refused further inquiry. No further medical information expected.
15-Jul-2019	UAE; 19US041231; -; U.S.A	Species: Canine Breed: Welsh Corgi Sex: M Sex qualifier: Neutered Age: 6.00 Year(s) Weight: 30 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: Unknown Heartworm Medication; Route: Topical / Cutaneous Was the product used ok?: Yes	06-Jul-2019*	07-Jul-2019	1 Day(s)	D-D	Suspected Adverse Event: On 15 Jul 2019, a B.I. employee reported the following event for Chase, a 30 pound, 6 year old, male neutered Welsh Corgi mix. 6 Jul 2019: 1 vial of FRONTLINE PLUS DOG 23-44 LBS (lot unknown) was applied in one are between the shoulder blades. 7 Jul 2019: The dog had mucus in stools and was reluctant to eat his food. It is unknown how long the symptoms went on. 8 Jul 2019: The dog recovered. It is unknown how long the dog has been on FRONTLINE PLUS. The dog is also on an unknown heartworm medicin since unknown date. The dog was not seen by the veterinarian. No further information.
15-Jul-2019	UAE; 19US041237; PA; U.S.A	Species: Canine Breed: Lhasa Apso Sex: M Sex qualifier:	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON	12-Apr-2019	26-Apr-2019	N/A	D-D	Suspected Lack of Efficacy Claim: On 15 Jul 2019, a pet owner reported the following event for Charlie, a 10 year old, 28 pound, neutered male Lhasa Apso. 12 Apr 2019: The dog received the first monthly application of FRONTLINE PLUS DOG 23-44 LBS (R62540BL), topically

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 384 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

v1.2

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00391

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Neutered Age: 10.00 Year(s) Weight: 28 lbs				Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes					between the shoulder blades in one location. 26 Apr 2019: The pet owner took the dog on a hike and found several live ticks crawling on him that day. The pet owner removed the ticks. 8 Jul 2019: The pet owner found 1 live flea on the dog's stomach. 12 Jul 2019: The dog received the most recent application of FRONTLINE. 15 Jul 2019: The dog was chewing at its back legs and the pet owner found 1 live flea on the dog. There are no other pets in the household and the pet owner lives in an apartment complex. The pet owner is not noticing any fleas inside of the home and is not getting bit. No further information expected.
15-Jul-2019	UAE; 19US041261; NY; U.S.A	Species: Feline Breed: Feline (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: 9 lbs	2	2	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	05-Jul-2019*	07-Jul-2019*	2 Day(s)	D-D	Suspected Adverse Event: On 15 July 2019, the owner reported the following event for 2 felines of average weights (all other signalments unknown). 5 July 2019*: One vial of FRONTLINE PLUS CATS (S40603) was applied between the shoulder blades, by the pet owner to both cats. 7 July 2019*: The cats had started to extremely itch. 12 July 2019: The cats present to clinic. The cats had fleas. The clinic administered an unknown amount of cap star and an unknown injection to the cats. Also the clinic performed bloodwork and physical exam. 13 July 2019: The cats recovered. No further medical information is expected.
15-Jul-2019	UAE; 19US041262; NY; U.S.A	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: M Sex qualifier: Neutered Age: 5.00 Year(s) Weight: 9 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	08-Jun-2019	05-Jul-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 15 Jul 2019, the pet owner reported the following event for Gingie, a 5 year old, 9 pound, male neutered, Domestic Shorthair. 8 Jun 2019: The patient got his monthly dose FRONTLINE PLUS CATS(S40502AX) from an 8 pack. This was applied correctly to the cat. The cat has been on FRONTLINE PLUS since 2013* monthly. 4 Jul 2019: The patient got his monthly dose of FRONTLINE PLUS CATS(S40502AX). This was applied correctly to the cat. 5 Jul 2019*: Fleas were seen on the cat. The cat is mostly indoors, but does go outside once daily. The owner stated she did not give anything else to the cat other than the FRONTLINE. The owner is seeing fleas in the household, on herself, and on her son. She has treated the house with Knockout Spray. The patient's current condition is ongoing. There a total of 2 felines in the household, the other cat also has a case please see 19US042774. No further medical information expected.
15-Jul-2019	UAE; 19US041267; PA; U.S.A	Species: Canine Breed: Pomeranian Sex: F Sex qualifier: Neutered Age: 7.50 Year(s) Weight: 14.0 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-Jun-2019	15-Jun-2019*	N/A	D-D	Suspected Lack of Efficacy Claim: On 15 Jul 2019, the animal owner reported the following event for Jasmine, a 7.5 year old*, 14.0 pound, spayed female Pomeranian 01 Apr 2019, 01 May 2019, 01 Jun 2019, and 01 Jul 2019: She received FRONTLINE PLUS DOG 5-22 LBS (S62502AW) one dose applied topically monthly between the shoulders. 15 Jun 2019*: She began experiencing pruritus. She did not present to the veterinary clinic. No treatments have been initiated. 15 Jul 2019: The owner noticed a small amount of fleas on the pet. The owner has not been noticing fleas off of the pet inside the home. The dog does frequently get leashed walked. She has not presented to the veterinary clinic. No treatments have been

N/A signifies the information for this field is either not available or not applicable

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

Report printed on 25-Oct-2019 at 8:39:59PM

*indicates Approximate date or weight

Page 385 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00392

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						ok?: Yes					performed. Her current condition is ongoing. The owner bathes the pet every other month with a pet approved shampoo. The owner did not notice fleas on the pet prior to application. There are no other pets in the household. No further medical information expected.
15-Jul-2019	UAE; 19US041277; MD; U.S.A	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	09-Jul-2019	09-Jul-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 15 Jul 2019, the technician reported the following event for a canine with unknown signalment. Unknown date, Jan 2019*: The dog began receiving FRONTLINE PLUS DOG (unsubstantiated) (lot unknown, package unavailable) monthly with unknown purchase history. The product's application details are unknown. It is unknown if fleas were seen prior to product application. 9 Jul 2019: The monthly dose was applied. The owner is noticing fleas. The dog's excursion history is unknown. 15 Jul 2019: The owner is still noticing fleas. The dog presented to the veterinary clinic. It is unknown if any diagnostics have been performed. Treatments have been initiated with NEXGARD (unsubstantiated (lot and expiration unknown). The dog's current condition is ongoing. It is unknown how many animals are in the household. Caller did not wish to provide any further details. No further medical information expected.
15-Jul-2019	UAE; 19US041278; KS; U.S.A	Species: Canine Breed: Chihuahua Sex: F Sex qualifier: Neutered Age: 12.00 Year(s) Weight: 5 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: Aveeno Baby Shampoo; Route: Topical / Cutaneous Was the product used ok?: Yes	08-Jul-2019	08-Jul-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 15 Jul 2019, the pet owner reported the following event for Abby, a 5 pound, 12 year old, female spayed, Chihuahua. 6 Jul 2019*: The owner bathed the dog in Aveeno Baby Shampoo. 8 Jul 2019: The dog was itching but no live fleas were seen. The owner applied 1 vial of FRONTLINE PLUS DOG 5-22 LBS(R60308AL) was applied to the dog in one area between the shoulder blades. The owner has seen 1-5 fleas on the dog since the application. The dog is primarily indoors, goes outside briefly for potty break in a yard that has been treated for fleas. The dog goes on short walks in the neighborhood. No urban wildlife or stray pets have been seen in the area. There was one other dog in the home who was treated with FRONTLINE who not having an issue with fleas. No further information.
15-Jul-2019	UAE; 19US041295; FL; U.S.A	Species: Canine Breed: Schnauzer (Miniature) Sex: M Sex qualifier: Neutered Age: 2.00 Year(s) Weight: 15 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: Perfect Coat White Pearl Shampoo; Unknown Pet Shampoo; Route: Topical / Cutaneous Was the product used ok?: Yes	01-Apr-2019	17-Jun-2019	N/A	D-D	Suspect Adverse Event and Suspected Lack of Efficacy Claim : On 15 Jul 2019, the owner reported the following event for Roscoe, a 2 year old (16 Apr 2017), 15 pound, male neutered, Miniature Schnauzer. 01 Apr 2019, 01 May 2019, and 01 Jun 2019: One vial of FRONTLINE PLUS FOR DOGS 5-22 LBS (S62106AL) was applied between the shoulder blades. 08 Apr 2019*, 08 May 2019*, and 08 Jun 2019*: The owner bathed the dog with Perfect Coat White Pearl Shampoo. 17 Jun 2019: The dog presented to the groomer and was bathed with an unknown pet shampoo. The groomer saw an unknown number of fleas on the dog. 01 Jul 2019: One vial of FRONTLINE PLUS FOR DOGS 5-22 LBS (S62106AL) was applied between the shoulder blades. 08 Jul 2019: The owner bathed the dog with Perfect Coat White Pearl Shampoo. The dogs hair became discolored with a yellowish tint, at the area of product application. 15 Jul 2019: Owner does not see any fleas on the dog but discoloration is still there.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
 Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
 *indicates Approximate date or weight

Page 386 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00393

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											Dog has not been seen by the veterinarian. Dog is mainly indoor but does go outside to go to the bathroom. Owner is not getting bit. Owner lives on a preserve and there are a lot of other animals outside. No further medical information expected.
15-Jul-2019	UAE; 19US041301; OR; U.S.A	Species: Canine Breed: Pomeranian Sex: M Sex qualifier: - Age: 11.00 Year(s) Weight: 9.5 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: Vetmedin pimobendan chewable 2.5 mg NP; unknown manufacturer's furosemide; benazepril; Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not respected)	12-Jul-2019	13-Jul-2019	1 Day(s)	D-C	Suspected Adverse Event: On 15 Jul 2019, the animal owner reported the following event for Tommy, a 11 year old*, 9.5 pound, intact male Pomeranian. 12 Jul 2019: He received FRONTLINE PLUS DOG 5-22 LBS (P60814AL) one vial applied topically down the back. He concurrently received VETMEDIN (PIMOBENDAN) 2.5 MG CHEWABLE TABLET (lot and expiration unknown) 0.29 mg/kg (1/2 tab) PO twice daily; an unknown manufacturer's furosemide unknown dosage at an unknown interval; and benazepril an unknown dosage at an unknown interval. 13 Jul 2019: He began experiencing anorexia and ataxia. He has not presented to the veterinary clinic. No treatments have been performed. His current condition is ongoing. He previously received a FRONTLINE PLUS monthly since at least 12 May 2019 with no adverse effects noted. He previously received VETMEDIN twice daily for a few months with no previous adverse effects noted. He has a pertinent medical history of undefined cardiac issues. No further medical information expected. UPDATE On 05 Sep 2019: No new information received. No further medical information expected.
14-Jul-2019	UAE; 19US041304; CA; U.S.A	Species: Canine Breed: Pit Bull Sex: M Sex qualifier: Neutered Age: 5.00 Year(s) Weight: 70.000 lbs*	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-Apr-2019*	01-Apr-2019*	0 Day(s)	D-D	Suspected Lack of Efficacy Claim and Suspected Adverse Event : On 14 Jul 2019, the pet owner reported the following event, through Safety Call International (SCI) for Buddy, a 70 pound*, 5 year old*, Pit Bull. 01 Apr 2019*: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown) topically between the shoulder blades for the first time. The dog still had an unknown number of fleas and ticks present. 01 May 2019*, 01 Jun 2019*, and 01 Jul 2019*: The pet owner applied the full contents of 1 vial of FRONTLINE PLUS DOG 45-88 LBS (lot unknown) topically between the shoulder blades. The dog still had an unknown number of fleas and ticks present. 14 Jul 2019: The owner found an unknown number of fleas and ticks on the dog. The dog is scratching and has bumps all over. Owner cleans bedding regularly and there is no carpet or furniture in the house. It is unknown if fleas and ticks are still present. No further medical information expected.
15-Jul-2019	UAE; 19US041314; AL; U.S.A	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: M Sex qualifier: Neutered Age: 2.00 Year(s) Weight: 10 lbs	1	1	1	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous	20-Jun-2019	20-Jun-2019*	0 Day(s)	D-A	Suspected Adverse event: On 15 Jul 2019, the owner reported the following event for Thor, 2 year old, 10 pound, male neutered, Domestic Shorthair. 20 June 2019: One vial FRONTLINE PLUS CATS (S41003AW) was applied topically in between the shoulder blades in one location. Within 24 hours the cat became extremely lethargic, stumbling around, and not eating/drinking. 21 Jun 2019: The pet was presented to the emergency clinic. The cat was given treatment with IV fluids, Interferon alpha, and B-12

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 387 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00394

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Was the product used ok?: Yes					<p>Injections.</p> <p>22 Jun 2019: The cat passed away at the clinic.</p> <p>This is the first dose of FRONTLINE applied to the cat. There are 5 other cats within the home that experienced a lack of efficacy while using the product, 19US041315. No further medical information expected at this time.</p> <p>20 Aug 2019, Per medical records from emergency hospital received 15 Aug 2019, on presentation patient was febrile (103.0 F), shaky, nonambulatory, and grossly jaundiced. No diagnostics were performed. Patient was treated with inpatient supportive care. Attending veterinarian's differential diagnoses included feline infectious peritonitis, hepatitis, and hepatic failure. No further information is expected.</p>
15-Jul-2019	UAE; 19US041339; -, U.S.A	Species: Canine Breed: Maltese Sex: M Sex qualifier: Neutered Age: 2.00 Year(s) Weight: 7.5 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: unknown OTC flea and tick topical; Route: Topical / Cutaneous Was the product used ok?: Yes	29-Jun-2019	13-Jul-2019	2 Week(s)	D-D	<p>Suspected Lack of Efficacy Claim: On 15 Jul 2019, the owner reported the following event for Rusty, a 7.5 pound, 2 year old*, neutered male Maltese and Toy Poodle mix.</p> <p>Jun 2019*: Owner noticed that Rusty was scratching allot more while on another unknown OTC flea and tick topical.</p> <p>29 Jun 2019: The owner applied 1 dose of FRONTLINE PLUS DOG 5-22 LBS (S611006AL), topically in between the shoulder blades.</p> <p>13 Jul 2019: The owner noticed Rusty still scratching at this paws and saw an unknown amount of fleas and "flea eggs".</p> <p>14 Jul 2019: Rusty was bathed in an unknown pet approved shampoo.</p> <p>Rusty is considered an indoor dog that goes outside for occasional walks and potty breaks. This was his first time receiving the FRONTLINE product. There were no fleas seen prior to product use. No further information at this time.</p>
15-Jul-2019	UAE; 19US041356; NC; U.S.A	Species: Canine Breed: Beagle Sex: M Sex qualifier: Neutered Age: 18.00 Month(s) Weight: 26 lbs	3	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: IVERMECTIN/P YRANTEL PAMOATE CHEWABLE 136MCG/326MG ; Route: Topical / Cutaneous Was the product used ok?: Yes	12-Jul-2019	12-Jul-2019	0 Day(s)	D-D	<p>Suspected Adverse Event: On 15 Jul 2019, the owner reported the following event for Opi, 1 year old, 26 pound, neutered male, Beagle canine.</p> <p>12 Jul 2019: One chew of HEARTGARD PLUS (136MCG/114MG) (Lot and exp unknown) was administered orally. One vial of FRONTLINE PLUS DOG 23-44 LBS (lot and expiration unknown) was applied between the shoulder blades. After 4.5 hours the dog experienced vomiting. The pet did not present to the clinic and no treatment was provided.</p> <p>The dog has received both products monthly since 2018* with no issue. There are 2 other dogs in the household that received both product and experienced no issue. No further medical information is expected.</p>
15-Jul-2019	UAE; 19US041361; PA; U.S.A	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: X Sex qualifier: Neutered Age: 11.00	3	3	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products	15-Jun-2019	07-Jul-2019	0 Day(s)	D-D	<p>Suspected Lack of Efficacy Claim: On 15 Jul 2019 a pet owner reported the following event for 3 11 month old (16 Jul 2018), neutered Domestic Shorthair cats, of mixed sex who are 8 to 10 pounds.</p> <p>12 May 2019, 15 Jun 2019, 7 Jul 2019: Owner applied 1 vial FRONTLINE PLUS CATS (lot unknown) to the skin between the shoulder blades of each cat.</p> <p>7 Jul 2019: Owner saw an unknown amount of fleas on cats for the</p>

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 388 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00395

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Month(s) Weight: 8 - 10 lbs				Route: Topical / Cutaneous Was the product used ok?: Yes					first time and reapplied FRONTLINE PLUS. The cats live inside and go outside on leash in yard, which is a grassy area that is unfenced. The owner sees rabbits, squirrels, and bears on the property. The cats do not receive baths. The cats have had not skin problems. The owner has not treated the home. Owner has not seen fleas in home and is not getting bitten. The owner is still seeing fleas on the cats. No further medical information expected.
15-Jul-2019	UAE; 19US041383; NC; U.S.A	Species: Canine Breed: Terrier (Jack Russell) Sex: M Sex qualifier: - Age: 21.00 Year(s) Weight: 22.0 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-Jul-2019	04-Jul-2019*	3 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 15 Jul 2019, the animal owner reported the following event for Hercules, a 21 year old*, 22.0 pound, intact male Jack Russell Terrier. 01 Jul 2019: He began receiving FRONTLINE PLUS DOG 5-22 LBS (S62502AW) one dose applied topically for the first time. 04 Jul 2019*: The owner noticed a small amount of fleas on the pet. He began experiencing pruritus. The owner has not been noticing fleas off of the pet inside the home. The dog does frequent grass areas around the apartment. He has not presented to the veterinary clinic. No treatments have been performed. His current condition is ongoing. The owner bathes the pet once a month with an oatmeal based shampoo prior to application. The owner did not notice fleas on the pet prior to application. There are no other pets in the household. No further medical information expected.
15-Jul-2019	UAE; 19US041390; -; U.S.A	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: unknown Was the product used ok?: Unknown to Company	04-Jul-2019	15-Jul-2019*	11 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 15 Jul 2019, a pet owner reported the following event for a canine of unknown signment. 4 Jul 2019: The owner applied 1 dose of FRONTLINE PLUS DOG (product unsubstantiated)(lot unknown). 15 Jul 2019: The owner saw fleas. All further details are unknown as there was a language barrier with the reporter. No further medical information expected.
15-Jul-2019	UAE; 19US041407; NY; U.S.A	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: F Sex qualifier: Neutered Age: 11.00 Year(s) Weight: 14.8 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	12-Jul-2019	13-Jul-2019	1 Day(s)	D-D	Suspected Adverse Event: On 15 Jul 2019, the pet owner reported the following event for Sweetie Pie, an 11 year old*, 14.8 pound, spayed female Domestic Shorthair. Apr 2015*: The cat began receiving FRONTLINE PLUS CATS (F10414AW) seasonally, during the warmer months each year. 12 Jul 2019: The most recent date of application. This was the first application this year. The pet owner applied the dose topically between the shoulder blades. 13 Jul 2019: The cat lost all her hair at the application site. The cat presented to the veterinary clinic. The veterinarian confirmed that the skin is not inflamed or further irritated. No diagnostics were performed. No treatment was provided. The cat's current condition is unknown. The cat previously received FRONTLINE PLUS CATS since Apr 2015* with no previous adverse effects. The pet owner did mentioned he purchased this box a year ago, and the box was still sealed. The pet owner was concerned this was a bad batch of the product. No further medical information expected. Product Quality: On 15 Jul 2019, the reported reported the

N/A signifies the information for this field is either not available or not applicable

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

Report printed on 25-Oct-2019 at 8:39:59PM

*indicates Approximate date or weight

Page 389 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00396

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
											<p>following product quality issue with 1 dose out of a 3 pack of FRONTLINE PLUS CATS (F10414AW). This package was purchased online through Chewy.com a year ago, but has remained sealed until this dose. The pet owner applied the dose topically between the shoulder blades. The next day all the cats hair fell out. The pet owner has strong concern that this may be due to faulty product. Product return of 2 doses expected. No further information expected.</p> <p>23-SEP-19 QA results received: Investigation completed for FIPRONIL 10%/S METHOPRENE 12% SPOT ON Lot# F10414AW, expiry . Case investigated by France - Toulouse.</p> <p>Final complaint evaluation A product quality complaint for FRONTLINE PLUS CATS, batch number F10414AW, was received by BIAH QA on the 19th of July 2019. The complaint description is: AE.</p> <p>This defect is rare, it represents 0.1 ppm of every batch produced in 2017 (9 complaints for 78 447 597</p>
15-Jul-2019	UAE; 19US041416; -, U.S.A	Species: Feline Breed: Siamese Sex: F Sex qualifier: Neutered Age: 1.00 Year(s) Weight: 6 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	12-Jul-2019	15-Jul-2019	3 Day(s)	D-D	<p>Suspected Lack of Efficacy Claim: On 15 Jul 2019, the owner reported the following event for Chop cat, a 6 pound, 1 year old*, spayed female Siamese mix.</p> <p>12 Jul 2019: The owner applied 1 dose of FRONTLINE PLUS CATS (Lot Unknown), topically in between the shoulder blades.</p> <p>15 Jul 2019: The owner reported seeing an unknown amount of fleas.</p> <p>Chopcat is an indoor cat and there are no visible fleas in the home. It was confirmed over the phone that owner was using foreign label product. The remaining info is unknown as owner disconnected call: were fleas seen prior to product use and if this was the cat's first time receiving product. No further information at this time.</p>
15-Jul-2019	UAE; 19US041423; CA; U.S.A	Species: Canine Breed: Canine (unknown) Sex: U Sex qualifier: Unknown Age: 6.00 Year(s) Weight: 22.0 - 30.0 lbs*	3	3	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-Jul-2019	14-Jul-2019	13 Day(s)	D-D	<p>Suspected Lack of Efficacy Claim: On 15 Jul 2019, the animal owner reported the following event for three canines of unknown breed, 6 to 12 years old*, 22.0 to 30.0 pounds*, otherwise unknown signalment.</p> <p>01 Jul 2019: The canines received FRONTLINE PLUS DOG 23-44 (S61602AX) one dose per one canine applied topically to the neck for the first time.</p> <p>14 Jul 2019: The owner noticed a moderate amount of fleas on the canines. The owner has been noticing fleas off of the canines inside the home. The canines do frequent the grass and tree covered yard. They have not presented to the veterinary clinic. No treatments have been performed. Their current condition is ongoing.</p> <p>The owner bathes the canines every three days with Dawn dish soap. The owner did notice fleas on the canines and in the household prior to application. There are no other pets in the household. No further medical information expected.</p> <p>UPDATE 25 Jul 2019: After further review, the date first valid was corrected. No further medical information expected.</p>
09-Jul-2019	UAE; 19US041433; AR; U.S.A	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: F	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON	01-May-2019*	01-Jun-2019*	31 Day(s)	D-D	<p>Suspected Lack of Efficacy: On 9 Jul 2019, the pet owner reported the following event for Poppy, a 3 month old, 3.5 pound, intact female, Domestic Shorthair.</p> <p>1 May 2019*: The patient received her first dose of FRONTLINE PLUS CATS(S41004AW). This was applied correctly.</p>

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM
Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)
*indicates Approximate date or weight

Page 390 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00397

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Sex qualifier: - Age: 3.00 Month(s) Weight: 3.5 lbs				Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes					1 Jun 2019*: The patient received another dose of FRONLINE PLUS CATS(S41004AW). At this time fleas were seen on the animal. An hour after the patient became non responsive and went limp, see case 19US039974. The owner washed the cat with Dawn dish soap. The cat is stated to be indoor only, and there are no other animals in the house. The owner is seeing fleas in the house, but not on himself. The owner is seeing roughly one flea a day. The owner stated the FRONLINE was the only thing the cat had gotten at the time of dosing, and the cat as no prior reactions. The cat's current flea condition is ongoing. No further medical information expected.
16-Jul-2019	UAE; 19US041445; PA; U.S.A	Species: Canine Breed: Retriever (Labrador, Yellow) Sex: U Sex qualifier: Unknown Age: - Weight: 50 - 60 lbs*	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	02-Jul-2019	02-Jul-2019	0 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 16 Jul 2019, the pet owner reported the following event for a 50 to 60 pound*, Retriever (Labrador, Yellow) mix. 2 Jul 2019: There were a large amount of fleas on the dogs. The owner applied 1 vial of FRONLINE PLUS DOG 45-88 LBS(lot unknown) to the dog in one area between the shoulder blades. The owner has seen a large amount of fleas on the dog since the application. 15 Jul 2019: Owner applied a different product. The owner has been treating the dog monthly since Jan. 2019. The dog had a flea bath with an unknown shampoo prior to the first application in Jan. There are no fleas in the home biting the humans. The dog goes out for potty breaks and recreation in the yard. There are 2 other dogs in the home treated with FRONLINE having an issue with fleas. See cases 19US043468 and 19US041445. No further information.
16-Jul-2019	UAE; 19US041447; -; U.S.A	Species: Feline Breed: Feline (unknown) Sex: M Sex qualifier: Unknown Age: - Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-Jan-2019*	02-Jul-2019*	1 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 16 Jul 2019, the pet owner reported the following event for a male cat of further unknown signalment. 1 Jan 2019*: The patient got a dose of FRONLINE PLUS CATS(Unsubstantiated)(lot unknown). 22 Jan 2019*: The owner saw some fleas on the cat. It is unknown if the cat's condition improved or not. 1 Jul 2019*: The patient got a dose of FRONLINE PLUS CATS(Unsubstantiated)(lot unknown). An unknown amount of time later the owner noticed flea dirt on the cat, but no fleas. The owner stated the cat is outside most of the day and free roams in the area. It is unknown if the animal got any further treatments, and it's medical history is unknown. It is also unknown if fleas were being seen in the house or on the owner. It is also unknown how long it has been on FRONLINE prior, or if the cat is dosed monthly or not. The patient's current condition is ongoing. There a total of 2 felines in the household. Further information is unknown as owner refused further inquiry. No further medical information expected.
16-Jul-2019	UAE; 19US041470; -; U.S.A	Species: Canine Breed: Shepherd Dog (Others) Sex: F Sex qualifier: Neutered Age: 9.00 Year(s)	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other	30-Jun-2019	05-Jul-2019	5 Day(s)	D-D	Suspected Adverse Event: On 16 Jul 2019, a pet owner reported the following event for Taz, a 9 year old, 51 pound, spayed female Shepherd. 2017: The dog started using FRONLINE PLUS DOG 45-88 (lot unknown) 1 dose topically between the shoulders without issue. It is unknown if the owner uses annually versus seasonally. 30 Jun 2019: The most recent dose was applied.

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 391 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00398

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
		Weight: 51 lbs				products Route: Topical / Cutaneous Was the product used ok?: Yes					5 Jul 2019: The owner noticed a pustule on the dog's back at unknown location and took the dog to a vet where they shaved and cleaned the area and found more. The dog was treated with an unknown antibiotic. No further medical information expected.
16-Jul-2019	UAE; 19US041491; WA; U.S.A	Species: Canine Breed: German Shepherd Dog Sex: F Sex qualifier: Neutered Age: 8.00 Year(s) Weight: 105 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	14-Jul-2019	14-Jul-2019	0 Day(s)	D-D	Suspected Adverse Event: On 16 Jul 2019, a pet owner reported the following event for Emme, an 8* year old, 105 pound, spayed female German Shepherd. 14 Jul 2019: The dog received 1 application of FRONTLINE PLUS DOG 89-132 LBS (S6015AR) topically between the shoulder blades in one spot for the first time. Late that evening, the dog began experiencing diarrhea. The dog has continued to have diarrhea. The dog has not presented to the clinic and no treatments have been performed. No further medical information expected.
16-Jul-2019	UAE; 19US041507; -; U.S.A	Species: Feline Breed: Calico Sex: F Sex qualifier: Neutered Age: 10.00 Year(s) Weight: Unknown	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-Feb-2019*	16-Jul-2019*	15 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 16 Jul 2019, the owner reported the following event for Callie, a 10 year old, spayed female Calico of unknown weight. Jan 2019*: The owner saw an unknown amount of fleas on Callie. Feb 2019*: Callie was started on FRONLTINE PLUS CATS (R41201AW), topcially in between the shoulder blades. 1 Jul 2019: The most recent dose was applied. Unknown Date: The owner saw a small to moderate amount of fleas and bathed the cat in Johnson & Johnson Baby Shampoo. 16 Jul 2019: Fleas were still being seen on the pet. Callie is an indoor cat and the only pet in the home. The owner does give the product year round, give or take a couple doses on unknown months. No further information at this time.
16-Jul-2019	UAE; 19US041509; MA; U.S.A	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: M Sex qualifier: Unknown Age: - Weight: 7 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	01-Jan-2019*	16-Jul-2019	15 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 16 Jul 2019, the pet owner reported the following event for a 7 pound feline of unknown signalment. Jan 2019*: The cat began receiving monthly doses of FRONTLINE PLUS CATS (R40801) with the most recent dose applied 24 hours after the cat was bathed on 1 Jul 2019*. The product was applied by the animal owner topically between the shoulder blades. 16 Jul 2019: The owner observed 1 tick on the cat and 1 tick in the home. The species of tick was not identified. The owner also observed less than 10 fleas on the cat. There are no other animals in the home. The cat spends time indoors and outdoors in a wooded yard. No further medical information expected.
16-Jul-2019	UAE; 19US041522; NC; U.S.A	Species: Canine Breed: Chihuahua Sex: F Sex qualifier: - Age: 4.00 Year(s) Weight: 10 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: Apoquel; Route: Topical / Cutaneous	04-Jul-2019	13-Jul-2019*	9 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 16 Jul 2019, the pet owner reported the following event for Baby, a 4 year old, 10 pound, intact female, Chihuahua. 4 Jul 2019: The patient got her most recent dose of monthly FRONTLINE PLUS DOG 5 - 22 LBS(S62106AL). The dog has been on FRONTLINE since 2016* monthly. The owner applied the dose correctly. Owner stated he has dealt with fleas before, but does not remember the exact dates of when he last had to deal with them. He stated it was a summer issue mostly, but had seen it in winter before once again exact dates are unknown. See case

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 392 of 867

Report : D:\Assured\crystal_reports\EPAreport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00399

Date case Received	Case type; Case Reference; State and Country of Occurrence	Patient	# Treated	# Reacted	# Died	Product(s)	Product Start Date	Date Reaction Started	Time to Onset	EPA Code	Event Narrative
						Was the product used ok?: Yes					19US043183. 13 Jul 2019*: The owner noticed fleas on the animal. The owner stated the animal does itch when the fleas occur. The dog does go for walks and gets an occasional bath. There are no fleas in the house currently, and no fleas on the owner. He now treats the house with Adams Carpet Powder. The patient's current condition is ongoing. There a total of 1 canine and 1 feline in the household, this feline is on Advantix and has no issues at the moment. The patient has a pertinent medical history of flea dermatitis in Apr 2019*, this was treated with daily Apoquel. No further medical information expected.
16-Jul-2019	UAE; 19US041533; IL; U.S.A	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: F Sex qualifier: Neutered Age: 2.00 Year(s) Weight: Unknown	2	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	09-Jul-2019*	16-Jul-2019	1 Week(s)	D-D	Suspected Adverse Event: On 16 July 2019, the owner reported the following event for Mittens, a 2 year old, spayed female Domestic Shorthair (weight unknown by reporter). *9 Jul 2019: One vial of FRONTLINE PLUS CATS (S40502AX) was topically applied to the skin between the shoulder blades. 16 July 2019: The cat developed a large dandruff flakes. The owner is monitoring the cat's condition, the cat has been on FL since April and has had the same symptoms a week or two after the treatment. How long the symptoms last varies month to month, the cat has had the same symptoms after receiving Pet Armor and Revolution in the past. There is one other cat in the home who did not have any symptoms. No further information available.
16-Jul-2019	UAE; 19US041545; MO; U.S.A	Species: Canine Breed: Australian Shepherd Sex: F Sex qualifier: Neutered Age: 10.00 Year(s) Weight: 59 lbs	1	1	0	Product used: FIPRONIL 10%/S METHOPRENE 9% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: Yes	12-May-2019	16-Jul-2019	4 Day(s)	D-D	Suspected Lack of Efficacy Claim: On 16 Jul 2019, the owner reported the following event for Semper, 10 year old, 59 pound, spayed female, Australian Shepherd canine. Unknown date: The owner started to notice fleas on the dog. 12 May 2019: One vial of FRONTLINE PLUS DOG 45-88 LBS (S61101AR) was applied between the shoulder blades for the first time this year. 13 May 2019: The flea issue persisted. 12 Jun 2019 and 12 Jul 2019: Another vial was applied. 16 Jul 2019: The fleas issue is still ongoing. The dog has access to a fenced in yard. The dog has received the product on prior unknown dates with no issue. There are 3 cats in the household also receiving FRONTLINE and experiencing an issue (see case 19US0). No further medical information is expected.
16-Jul-2019	UAE; 19US041555; TN; U.S.A	Species: Feline Breed: Domestic Shorthair (Crossbreed) Sex: M Sex qualifier: Neutered Age: 2.00 Year(s) Weight: 19.2 lbs	4	1	0	Product used: FIPRONIL 10%/S METHOPRENE 12% SPOT ON Other products used: no other products Route: Topical / Cutaneous Was the product used ok?: No (Treatment / vaccination program not	02-Apr-2019*	09-Jul-2019*	1 Week(s)	D-D	Suspected Lack of Efficacy Claim: On 16 Jul 2019, the animal owner reported the following event for Sam, a 2 year old*, 19.2 pound, neutered male Domestic Shorthair. 02 Apr 2019*: He began receiving FRONTLINE PLUS CATS (R40719AW) one dose applied topically monthly to the neck. 02 Jul 2019: The most recent application. 09 Jul 2019*: He began experiencing pruritus. The owner noticed a small amount of fleas on the pet. The owner has not been noticing fleas off of the pet inside the home. The feline does frequent wooded outdoor environment. He has not presented to the veterinary clinic. No treatments have been performed. His current condition is ongoing. The owner does not bathe the pet. The owner did notice fleas on the pet prior to application. There a total of four felines in the household, the other three felines have been treated with the FRONTLINE PLUS CATS. The owner is not seeing fleas on the

N/A signifies the information for this field is either not available or not applicable

Report printed on 25-Oct-2019 at 8:39:59PM

Sex Codes: M = Male, U = Unknown, Mixed = Mixed population – male(s) and female(s)

*indicates Approximate date or weight

Page 393 of 867

Report : D:\Assured\crystal_reports\EPAREport.p2.4.rpt

v1.2

In accordance with global BIAH policy, legal requirements, and regulations, BIAH records all adverse events (AE).

Collection of an AE report does not constitute an admission by BIAH that our product caused or contributed to the AE.

Confounding factors such as concurrently administered drugs, environmental factors, and medical history of the animal must be considered when evaluating AE reports.

ED_005739D_00014390-00400